TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

FEBRUARY 2013 REPORT

CHAPTER 8.5.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.5.1.

~~**Introduction**~~

1) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla,* and *Camelus bactrianus* with foot and mouth disease virus (FMDV).

2) The following defines the occurrence of FMDV *infection*:

   Detection in a sample from an animal listed above, of the virus, viral antigen, nucleic acid or virus-specific antibodies that are not a consequence of *vaccination* by a test as specified in the *Terrestrial Manual*.

3) The following defines the occurrence of FMDV circulation:

   Transmission of FMDV, as demonstrated by clinical signs or change in virological or serological status indicative of recent *infection*.

4) For the purposes of the *Terrestrial Code*, the *incubation period* ~~for~~ of FMD shall be 14 days.

5) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with FMDV. Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contact between them. Amongst *Camelidae* only Bactrian camels (*Camelus bactrianus*) are of sufficient susceptibility to have potential for epidemiological significance. South American camelids and dromedaries are not considered of epidemiological importance.

~~For the purposes of this chapter, ruminants include *animals* of the family of Camelidae (except *Camelus dromedarius*).~~

~~For the purposes of this chapter, a *case* is an *animal* infected with FMD virus (FMDV).~~

6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV circulation. FMDV *infection* in ruminants may persist leading to carriers. Although live FMDV can be recovered from carriers, transmission of FMDV from these carriers has not been proven, except from ~~for~~ African buffalo (*Syncerus caffer*).

7) The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with FMDV in the absence of clinical signs.

~~The following defines the occurrence of FMDV *infection:*~~

~~1. FMDV has been isolated and identified as such from an *animal* or a product derived from that *animal*; or;~~

~~2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more *animals*, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or~~

~~3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more *animals* showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.~~

Annex XXXIX (contd)

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.5.2.

FMD free country or zone where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.3. should be followed.

Susceptible *animals* in the FMD free country *or zone* where *vaccination* is not practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that effectively prevent the entry of the virus into the free country or *zone*~~,~~. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*~~,~~. ~~T~~these measures may include a *protection zone*.

To qualify for inclusion in the existing list of FMD free countries or *zones* where *vaccination* is not practised, a Member should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that within the proposed FMD free country or *zone*:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV *infection* has been found during the past 12 months;

   c) no *vaccination* against FMD has been carried out during the past 12 months;

   ~~d) no vaccinated *animal* has been introduced since the cessation of vaccination;~~

3) supply documented evidence that for at least the past 12 months:

   a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

4) describe in detail and supply documented evidence that for at least the past 12 months these are properly implemented and supervised: ~~the boundaries and measures of a *protection zone*, if applicable.~~

   a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

   b) the boundaries and measures of a *protection zone*, if applicable;

   c) the system for preventing the entry of the virus into the proposed FMD free country or *zone*;

   d) the control of the movement of susceptible *animals* into the proposed FMD free country or *zone* in particular if the procedure described in Articles 8.5.8., 8.5.9. and 8.5.12. are implemented;

   e) no vaccinated *animal* has been introduced during the past 12 months except in accordance with Articles 8.5.8. and 8.5.9.

The Member or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is not practiced only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

The status of a country or *zone* will not be affected by applying official emergency *vaccination* in zoological collections in the face of a clearly identifiable FMD threat, provided that the following conditions are met:

a) the zoological collection has a primary purpose to exhibit *animals* or preserve rare species and should be identified in advance, including the boundaries of the facility and be included in the country's contingency plan for FMD;

b) appropriate biosecurity measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;

c) the *animals* are identifiable as belonging to the collection;

d) the vaccine used complies with the *Terrestrial Manual*;

e) *vaccination* is conducted under the supervision of the *Veterinary Authority*;

f) the zoological collection is placed under active clinical *surveillance* for at least 12 months after *vaccination*.

In the event of the application for the status of an FMD free *zone* where *vaccination* is not practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is not practised, it should be indicated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

Article 8.5.3.

FMD free country or zone where vaccination is practised

In defining a *zone* where *vaccination* is practised the principles of Chapter 4.3. should be followed.

Susceptible *animals* in the FMD free country or *zone* where *vaccination* is practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that effectively prevent the entry of the virus into the free country or *zone*~~,~~. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*~~,~~ ~~T~~these measures may include a *protection zone*. Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible population.

To qualify for inclusion in the list of FMD free countries or *zones* where *vaccination* is practised, a Member should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that within the proposed FMD free country or *zone*:

   a) there has been no *outbreak* of FMD during the past two years;

   b) no evidence of FMDV circulation has been found during the past 12 months;

3) supply documented evidence that:

   a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

c) ~~routine~~ compulsory systematic *vaccination* in the target population is carried out ~~for the purpose of the prevention of FMD~~;

d) the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

4) describe in detail and supply documented evidence that these are properly implemented and supervised ~~the boundaries and measures of a *protection zone*, if applicable.~~:

a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of the virus into the proposed FMD free country or *zone* (in particular if the procedure described in Article 8.5.8. is implemented);

d) the control of the movement of susceptible *animals* into the proposed FMD free country or *zone*.

The Member or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of an FMD free country or *zone* where *vaccination* is practised wishes to change its status to FMD free country or *zone* where *vaccination* is not practised, it should notify the OIE in advance on the intended date of cessation of *vaccination* and apply for the new status within 24 months. The status of this country or *zone* remains unchanged until compliance with Article 8.5.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status will be suspended. If the country does not comply with requirements of Article 8.5.2., evidence should be provided within 3 months that they comply with Article 8.5.3. ~~the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred during that period.~~

In the event of the application for the status of an FMD free *zone* where *vaccination* is practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is practised, it should be indicated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

~~Article 8.5.4.~~

~~**FMD free zone where vaccination is not practised**~~

~~An FMD free *zone* where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such a *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.~~

To qualify for inclusion in the list of FMD free *zones* where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal *disease* reporting;

2. send a declaration to the OIE stating that within the proposed FMD free *zone*:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV *infection* has been found during the past 12 months;

   c) no vaccination against FMD has been carried out during the past 12 months;

   d) no vaccinated *animal* has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.;

3. supply documented evidence that:

   a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

4. describe in detail and supply documented evidence that these are properly implemented and supervised:

   a) the boundaries of the proposed FMD free *zone*;

   b) the boundaries and measures of a *protection zone*, if applicable;

   c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).;

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is not practised only after the submitted evidence has been accepted by the OIE.

The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.5.

FMD free zone where vaccination is practised

An FMD free *zone* where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* where vaccination is practised should be protected from neighbouring countries or *zones* if they are of a lesser *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where vaccination is practised, a Member should:

1. have a record of regular and prompt animal *disease* reporting;

2. send a declaration to the OIE that within the proposed FMD free *zone*;

   a) there has been no *outbreak* of FMD for the past two years;

   b) no evidence of FMDV circulation has been found during the past 12 months;

3. supply documented evidence that:

~~a) *surveillance* for FMD and FMDV *infection*/circulation in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;~~

~~b) regulatory measures for the early detection, prevention and control of FMD have been implemented;~~

~~c) routine vaccination is carried out for the purpose of the prevention of FMD;~~

~~d) the vaccine used complies with the standards described in the *Terrestrial Manual*;~~

~~4. describe in detail and supply documented evidence that these are properly implemented and supervised:~~

~~a) the boundaries of the proposed FMD free *zone*;~~

~~b) the boundaries and measures of a *protection zone*, if applicable;~~

~~c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).~~

~~The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~If a Member that has a *zone* which meets the requirements of a FMD free *zone* where vaccination is practised wishes to change the status of the *zone* to FMD free *zone* where vaccination is not practised, the status of this *zone* remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred in the said *zone* during that period.~~

Article 8.5.4~~6~~.

FMD free compartment

An FMD free *compartment* can be established in either an FMD free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible *animals* in the FMD free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member wishing to establish an FMD free *compartment* should:

1) have a record of regular and prompt animal *disease* reporting and if not FMD free, have an official control programme and a *surveillance* system for FMD in place according to Articles 8.5.4~~2~~40. to 8.5.4~~7~~42. and Article 8.5.4~~9~~46. that allows ~~an accurate~~ knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the FMD free *compartment* that:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV *infection* has been found during the past 12 months;

   c) either: ~~*vaccination* against FMD is prohibited;~~

      i) no *vaccination* against FMD has been carried out during the past 12 months; no vaccinated *animal* has been introduced during the past 12 months; or

      ii) compulsory systematic *vaccination* is carried out and the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

   ~~d) no *animal* vaccinated against FMD within the past 12 months is in the compartment;~~

   d~~e~~) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant articles in this chapter;

e~~f~~) documented evidence shows that *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation for FMD and FMDV *infection*;

f~~g~~) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

a) the animal subpopulation in the *compartment*; ~~and~~

b) the biosecurity plan ~~for FMD and FMDV *infection*~~ and, where applicable, the *vaccination* plan, to mitigate the risks identified by the *surveillance* carried out according to point 1 of Article 8.5.4.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *outbreak* of FMD has occurred within a ten-kilometre radius of ~~the *zone* in which~~ the *compartment* ~~is situated,~~ during the ~~last~~ past three months.

Article 8.5.5 ~~7~~.

FMD infected country or zone

For the purposes of this chapter, when the requirements for acceptance as an FMD free country or *zone* where *vaccination* is not practised or an FMD free country or *zone* where *vaccination* is practised are not fulfilled, such country or *zone* shall be considered as FMD infected. ~~an FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.~~

~~For the purposes of this chapter, an FMD *infected zone* is a *zone* that does not fulfil the requirements to qualify as either an FMD free *zone* where vaccination is not practised or an FMD free *zone* where vaccination is practised.~~

Article 8.5.6 ~~8~~.

Establishment of a containment zone within an FMD free country or zone

In the event of limited *outbreaks* within an FMD free country or *zone*, including within a *protection zone*, with or without *vaccination*, a single *containment zone*, which includes all ~~cases~~ *outbreaks*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

For this to be achieved and for the Member to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE that:

1) the boundaries of the *containment zone* are established taking into consideration that ~~the *outbreaks* are limited based on the following factors:~~ the *outbreaks* are limited based on the following factors:

a) immediately on suspicion, animal movement control has been imposed in the country or *zone*, and effective controls on the movement of other *commodities* mentioned in this chapter are in place ~~a rapid response including notification has been made~~;

~~b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;~~

~~c~~b) epidemiological investigation (trace-back, trace-forward) is able to demonstrate that the *outbreaks* are epidemiologically related and limited in number and geographic distribution ~~has been completed~~;

~~d) the *infection* has been confirmed~~;

~~e~~c) ~~the primary *outbreak* has been identified, and~~ investigations on the likely source of the *outbreak* have been carried out;

~~f) all *cases* have been shown to be epidemiologically linked;~~

~~g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;~~

2) a *stamping-out policy*, with or without the use of emergency *vaccination,* has been applied;

3) no new *cases* have been found in the *containment zone* within a minimum of one *incubation period* as defined in Article 8.5.1. after the application of a *stamping-out policy* to the last detected *case*;

~~3.~~4) the susceptible domestic and *captive wild* animal populations within the *containment zone*~~s~~ ~~should~~ are ~~be~~ clearly identifiable as belonging to the *containment zone*;

~~4.~~5) ~~increased passive and targeted~~ *surveillance* in accordance with Articles ~~8.5.42.3 to 8.5.47~~. 8.5.41., 8.5.42. and Article 8.5.~~49~~46. in the *containment zone* and in the rest of the country or *zone* ~~has been carried out~~ is in place ~~and has not detected any evidence of~~ FMDV *infection*;

~~5.~~6) animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

~~6. ongoing *surveillance* in the *containment zone* is in place.~~

The free status of the areas outside the *containment zone* ~~would be~~ is suspended ~~pending the establishment of~~ while the *containment zone* is being established. The free status of these areas may ~~could~~ be reinstated irrespective of the provisions of Article 8.5.~~9~~7., once the *containment zone* is clearly established, by complying with points 1 to 6 above. ~~The *containment zone* should be managed in such a way that it can~~ It should be demonstrated that *commodities* for *international trade* ~~can be shown to~~ have originated outside the *containment zone*.

In the event of recurrence of FMDV circulation in the *containment zone,* the approval of the *containment zone* is withdrawn.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.5.~~9~~7.

Article 8.5.7 ~~9~~.

Recovery of free status (see Figure 1)

1) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is not practised:

a) three months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.45. and 8.5.~~49~~46.; or

b) three months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.45. and 8.5.~~49~~46.; or

c) six months after the last *case* or the last *vaccination* (according to the event that occurs the latest), where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated *animals*, and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.~~47~~45. and Article 8.5.~~49~~46., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population. This period can be reduced to three months if additional *surveillance* in accordance to Article 8.5.45. is carried out.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.5.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. applies.

2) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or *zone* where *vaccination* is practised: 6 months after stamping out of the last *case* where a *stamping-out policy* has been applied and adoption of a continued *vaccination* policy, provided that serological *surveillance* is applied in accordance with Articles 8.5.40. to 8.5.42. and Articles 8.5.44. to 8.5.46, and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of FMDV circulation.

The country or *zone* can gain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. applies.

~~2.~~3) When an FMD *outbreak* or FMDV ~~*infection*~~ circulation occurs in an FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is practised:

a) 6 months after the last *case* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.42. and Articles 8.5.44. to 8.5.46~~8.5.45. and Article 8.5.49~~. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency *vaccination* and serological *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.42. and Articles 8.5.44. to 8.5.46. ~~8.5.47. and Article 8.5.49~~. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

~~3.~~4) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free *compartment*, Article 8.5.~~6~~4. applies. The waiting period in point 2a) and 2b) of Article 8.5.4. can be reduced to three months provided that the entire *compartment* has been depopulated, cleansed and disinfected.

5) Members applying for the recovery of status should do so as soon as the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this Article as soon as the *disease* has been successfully eradicated within the *containment zone*.

Article 8.5.8 ~~10~~.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (where vaccination either is or is not practised)

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *infected zone* if transported directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1) no FMD susceptible *animal* has been introduced into the *establishment* of origin and no *animal* in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the *animals* were kept in the *establishment* of origin for at least three months prior to movement;

3) FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for at least three months prior to movement;

4) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

5) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *infected zone*;

6) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be derived from *animals* that have been subjected to ante- and post-mortem inspection for FMD, with favourable results within 24 hours before and after *slaughter* and treated according to point 2 of Article 8.5.~~25~~22. or Article 8.5.~~26~~23. Other products obtained from the *animals* and any products coming into contact with them should be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.5.~~34~~31. to 8.5.~~41~~38.

Animals moved into a free *zone* for other purposes should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.5.~~14~~12.

Article 8.5.9~~11~~.

Direct ~~T~~ transfer ~~directly to slaughter~~ of FMD susceptible animals from a containment zone for slaughter in ~~to~~ a free zone (where vaccination either is or is not practised) ~~within a country~~

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *containment zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1) the *containment zone* has been officially established according to the requirements in Article 8.5.~~8~~6.;

2) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

3) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *containment zone*;

4) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be derived from *animals* that have been subjected to ante- and post-mortem inspection for FMD, with favourable results within 24 hours before and after *slaughter* and treated according to point 2 of Article 8.5.~~25~~22. or Article 8.5.~~26~~23. Other products obtained from the *animals* and any products coming into contact with them should be treated in such a way as to destroy any residual virus in accordance with Articles 8.5.~~34~~31. to 8.5.~~41~~38.

Article 8.5.10.~~12~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of FMD on the day of shipment;

2) were kept since birth or for at least the past three months in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised; ~~or a FMD free *compartment*~~

3) have not been vaccinated;

4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*~~.~~;

Article 8.5.11.~~13~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of FMD on the day of shipment;

2) were kept in an FMD free country, ~~or~~ *zone or compartment* where *vaccination* is practised, since birth or for at least the past three months; ~~and~~

3) when destined to an FMD free country or *zone* where *vaccination* is not practised, have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus ~~when destined to an FMD free country or *zone* where vaccination is not practised~~;

4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.5. 12.~~14~~.

Recommendations for importation from FMD infected countries or zones

For domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~the *animals*~~:

1) the *animals* showed no clinical sign of FMD on the day of shipment;

2) prior to isolation, the *animals* were kept in the *establishment* of origin ~~since birth, or~~

   a) for ~~the past~~ 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

   b) for ~~the past~~ 3 months, or since birth if younger than three months, if a *stamping-out policy* is not in force in the *exporting country*,

3) ~~and that~~ FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points 2 a) and b) above;

~~3~~4) the *animals* were isolated in an *establishment* or a *quarantine station* for the 30 days prior to shipment, and all *animals* in isolation were subjected to diagnostic tests (virus detection on a probang sample in ruminants or on throat swabs in pigs and serology) for evidence of FMDV *infection* with negative results on samples collected at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* or a *quarantine station* during that period; ~~or~~

4) ~~were kept in a *quarantine station* for the 30 days prior to shipment, all *animals* in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;~~

5) the *animals* were not exposed to any source of FMD *infection* during their transportation from the *establishment* or *quarantine station* to the *place of shipment*.

Article 8.5. 13.~~15~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For fresh semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

   c) were kept in an *artificial insemination centre* where none of the *animals* had a history of *infection*;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.14.~~16~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.15.~~17~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is practised;

   ~~c) if destined to an FMD free country or *zone* where vaccination is not practised:~~

   ~~i)~~c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

   ~~ii)~~d) had been vaccinated at least twice, with the last *vaccination* not more than 12 and not less than one month prior to collection;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

2~~3~~) the semen:

   a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

   b) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.16~~18~~.

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept in an ~~*establishment*~~ *artificial insemination centre* where no *animal* had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;

   c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

   d) had been vaccinated at least twice, with the last *vaccination* not more than 12 and not less than one month prior to collection;

~~2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

~~3~~.2) the semen:

a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

b) was subjected, with negative results, to a test for FMDV ~~*infection*~~ if the donor *animal* has been vaccinated within the 12 months prior to collection;

c) was stored in the country of origin for a period of at least one month following collection, and that during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.17.~~19.~~

Recommendations for the importation of *in vivo* derived embryos of cattle

Irrespective of the FMD status of the *exporting country*, *zone* or *compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.5.18.~~20.~~

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

a) showed no clinical sign of FMD at the time of collection of the oocytes;

b) were kept for at least three months prior to ~~at the time of~~ collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.5.~~15~~13., 8.5.~~16~~14., 8.5.~~17~~15. or 8.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.19.~~21~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least three months prior to collection in an FMD free country, or *zones* or *compartments* where *vaccination* is practised;

   ~~c) if destined for an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*:~~

   ~~i)~~c) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or

   ~~ii)~~d) had been vaccinated at least twice, with the last *vaccination* not less than one month and not more than 12 months prior to collection;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection~~;

2) fertilization was achieved with semen meeting the conditions referred to in Articles 8.5.~~15~~13., 8.5.~~16~~14., 8.5.~~17~~15. or 8.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.20.~~22~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For fresh meat or meat products of FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1) have been kept in the FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.;

2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

Article 8.5. 21.~~23~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For fresh meat and meat products of ruminants and pigs ~~cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1) have been kept in the FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is practised, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.;

2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results~~.~~;

3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, have been removed.

~~Article 8.5.24.~~

~~**Recommendations for importation from FMD free countries or zones where vaccination is practiced**~~

~~For fresh meat or meat products of pigs and ruminants other than cattle and buffaloes~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:~~

~~1) have been kept in the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;~~

~~2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.~~

Article 8.5.22.~~25~~.

Recommendations for importation from FMD infected countries or zones, where an official control programme for FMD, involving compulsory systematic vaccination ~~of cattle,~~ exists

For fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat*:

1) comes from *animals* which:

   a) have remained in the *exporting country* for at least three months prior to *slaughter*;

   b) have remained, during this period, in a part of the country where cattle and buffaloes are regularly vaccinated against FMD and where official controls are in operation;

   c) have been vaccinated at least twice with the last *vaccination* not more than 12 months and not less than one month prior to *slaughter*;

   d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and buffaloes were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;

   f) have been slaughtered in an approved *abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

   g) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;

2) comes from deboned carcasses:

   a) from which the major lymphatic nodes have been removed;

   b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 8.5.23.~~26~~.

Recommendations for importation from FMD infected countries or zones

For meat products of ~~domestic ruminants and pigs~~ FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the entire consignment of *meat* comes from *animals* which have been slaughtered in an *approved abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;

2) the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.~~34~~31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.5.24.~~27~~.

Recommendations for importation from FMD free countries~~,~~ ~~or~~ zones or compartments ~~(where vaccination either is or is not practised)~~ ~~or FMD free compartments~~

For milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in an FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.

Article 8.5.25.~~28~~.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

For milk, cream, milk powder and milk products

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products:

   a) originate from *establishments* ~~*herds or flocks*~~ which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.~~38~~35. and in Article 8.5.~~39~~36.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.26.~~29~~.

Recommendations for importation from FMD infected countries

For blood and meat-meals from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 8.5.27.~~30~~.

Recommendations for importation from FMD infected countries

For wool, hair, bristles, raw hides and skins from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.~~35~~32., 8.5.~~36~~33. and 8.5.~~37~~34.;

2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather – e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.5.28.~~31~~.

Recommendations for importation from FMD infected countries or zones

For straw and forage

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these *commodities*:

1) are free of grossly identifiable contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten minutes,

   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least three months (under study) before being released for export.

Article 8.5.29.~~32~~.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

For skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from *animals* that have been killed in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where *vaccination* either is or is not practised).

Article 8.5.30.~~33~~.

Recommendations for importation from FMD infected countries or zones

For skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 8.5.~~40~~37.

Article 8.5.31.~~34~~.

Procedures for the inactivation of the FMD virus in meat and meat products

For the inactivation of viruses present in *meat* and *meat products*, one of the following procedures should be used:

1. Canning

   Meat and *meat products* ~~is~~ are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, and *meat products* shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

   After cooking, ~~it~~ they shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

   When *rigor mortis* is complete, the *meat* must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

   'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 8.5.32.~~35~~.

Procedures for the inactivation of the FMD virus in wool and hair

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);

2) chemical depilation by means of slaked lime or sodium sulphide;

3) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;

4) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;

5) storage of wool at ~~18°C for four weeks, or~~ 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.5.33.~~36~~.

Procedures for the inactivation of the FMD virus in bristles

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1) boiling for at least one hour;

2) immersion for at least 24 hours in a 1 percent solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 8.5.34.~~37~~.

Procedures for the inactivation of the FMD virus in raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2 percent sodium carbonate.

Article 8.5.35.~~38~~.

Procedures for the inactivation of the FMD virus in milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1) a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or

2) if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature – short time pasteurisation [HTST]), or

3) if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 8.5.36.~~39~~.

Procedures for the inactivation of the FMD virus in milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1) the HTST process applied twice;

2) HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with dessication;

3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.5.37~~40~~.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of viruses present in skins and trophies from *wild animals* susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3) soaking, with agitation, in a 4 percent (w/v) solution of washing soda (sodium carbonate – Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours;

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 percent washing soda (sodium carbonate – Na_2CO_3).

Article 8.5.38.~~41~~.

Procedures for the inactivation of the FMD virus in casings of ruminants and pigs

For the inactivation of viruses present in casings of ruminants and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, ~~Aw~~ a_w< 0.80), or with phosphate supplemented ~~dry~~ salt containing 86.5 percent NaCl, 10.7 percent Na_2HPO_4 and 2.8 percent Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of greater than 12°C during this entire period.

Article 8.5.39.

OIE endorsed official control programme for FMD

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations*.

Members may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member's *official control programme* for FMD to be endorsed by the OIE, the Member should:

1) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;

2) submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;

3) submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:

   a) the timeline;

   b) the performance indicators to assess the efficacy of the control measures to be implemented;

   c) submit documentation indicating that the *official control programme* for FMD is applicable to the entire country;

4) submit a dossier on the epidemiology of FMD in the country describing the following:

   a) the general epidemiology in the country highlighting the current knowledge and gaps;

   b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate virus circulation in domestic ruminants in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of FMD susceptible *animals* and their products within and into the country;

5) submit evidence that FMD *surveillance* is in place:

   a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;

   b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;

6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:

   a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;

   b) detailed information on *vaccination* campaigns, in particular on:

      i) target populations for *vaccination*;

      ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

      iii) technical specification of the vaccines used and description of the licensing procedures in place;

      iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the *Veterinary Services*; or

– an increase in the incidence of FMD that cannot be addressed by the programme.

Article 8.5.40.~~42~~.

Surveillance: introduction

Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking establishment, maintenance and recovery of freedom from FMD at the country, *zone* or *compartment* level, either with or without the use of *vaccination* and Members seeking endorsement of their *official control programme* for FMD, in accordance with Article 8.5.39. *Surveillance* aimed at identifying *disease* and *infection*/virus circulation should cover all the susceptible species, including *wildlife*, if applicable, within the country, *zone* or *compartment*. ~~Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination, or a *compartment*, following an *outbreak* and for the maintenance of FMD status.~~

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is ~~impossible~~ inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of ~~FMD virus (~~FMDV~~)~~ should differ significantly from an application

designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*. *Surveillance* strategies employed for establishing and maintaining a *compartment* should also identify the prevalence, distribution and characteristics of FMD outside the *compartment* in the country or *zone. Surveillance* strategies employed in support of an OIE endorsed *official control programme* should show evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*. There is therefore considerable latitude available to Members to design and implement *surveillance* on the one hand to establish that the whole territory or part of it is free from FMDV *infection*/circulation and on the other to understand the epidemiology of FMD as part of the official FMD control programmes.

It is incumbent upon the Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are identified and managed. This should include provision of scientifically based supporting data. ~~There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.~~

Surveillance for FMD should be in the form of a continuing programme. The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed to establish the prevalence of FMDV *infection* or to demonstrate the absence of FMDV *infection*/circulation may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be an appropriate strategy. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). The Member should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination/infection* history and production class of *animals* in the target population.

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection*/circulation. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* as well as *herds* which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

– characterization of the existing production systems;

– results of clinical *surveillance* of the suspects and their cohorts;

– quantification of *vaccinations* performed on the affected sites;

– sanitary protocol and history of the *establishments* with positive reactors;

– control of *animal identification* and movements;

– other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

~~*Surveillance* for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.~~

~~For the purposes of this chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.~~

Article 8.5.41.~~43~~.

Surveillance: ~~general conditions and methods~~ general principles

1) A *surveillance* system in accordance with Chapter 1.4. should be ~~under~~ the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples ~~from suspect *cases* of FMD~~ to a *laboratory* for FMD diagnose~~i~~s ~~as described in the *Terrestrial Manual*~~. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.

2) The FMD *surveillance* programme should:

   a) include structured non-random *surveillance* activities as described in Article 1.4.5. with particular reference to an early warning system throughout the production, marketing and processing chain for reporting ~~suspicious~~ suspect *cases*. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect *cases* of FMD should be investigated immediately. ~~Where suspicion cannot be resolved by epidemiological and clinical investigation, s~~Samples should be taken and submitted for diagnostic testing ~~a *laboratory*~~, unless the suspect *case* can be confirmed or ruled out by epidemiological and clinical investigation. ~~This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.~~ Any *epidemiological unit* within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced;

   ~~b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to an FMD infected country or *infected zone* (for example, bordering a game park in which infected *wildlife* are present).~~

   b) implement structured population-based surveys, when appropriate, as described in Article 1.4.4.

3) The *surveillance* programme above should:

   a) identify the nature of risk factors, including the role of *wildlife*, to inform targeted *surveillance* strategies when appropriate;

   b) implement, when relevant, an appropriate combination of clinical investigation and other diagnostic procedures in high risk groups.

~~3~~4) An effective *surveillance* system should ~~will~~ periodically identify ~~suspicious~~ suspect *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Details of the occurrence of suspect *cases* and how they were investigated and dealt with should be documented. ~~The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV *infection*/circulation should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with.~~ This should include the results of diagnostic ~~*laboratory*~~ testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 8.5.42.~~44~~.

Surveillance: methods ~~strategies~~

~~1. Introduction~~

~~The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country, *zone* or *compartment*.~~

~~The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.~~

~~The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.~~

~~For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.~~

~~Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.~~

~~Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection*/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* which may be epidemiologically linked to it.~~

1~~2~~. Clinical surveillance

The detection of clinical signs by farmers, *veterinary para-professionals* and *veterinarians* is the foundation of an early warning system and of clinical *surveillance*. Clinical *surveillance* ~~aims at detecting clinical signs of FMD by~~ requires close physical examination of susceptible *animals*. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated~~. .~~ ~~It may~~ as it can ~~be able to~~ provide a high level of confidence of detection of *disease* if a sufficient~~ly large~~ number of clinically susceptible *animals* is examined at an appropriate frequency.

Clinical *surveillance* and ~~*laboratory*~~ diagnostic testing should ~~always~~ be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. ~~*Laboratory*~~ Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive ~~serology~~ laboratory tests. ~~Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.~~ Clinical *surveillance* may be insufficient in case of species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such cases, sero-surveillance should be used.

~~A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.~~

~~Identification of clinical *cases* is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such *animals*. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.~~

~~3~~2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide materials. It is essential that FMDV isolates are sent regularly to an OIE Reference Laboratory.

Virological *surveillance* ~~using tests described in the *Terrestrial Manual* should be conducted~~ aims to:

~~a)~~ ~~to monitor at risk populations;~~

~~b)~~a) ~~to~~ confirm clinically suspect *cases*;

~~c~~b) ~~to~~ follow up positive serological results;

c) characterize isolates for epidemiological studies and vaccine matching;

~~d)~~ ~~to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.~~

d) monitor at risk populations.

~~4~~3. Serological surveillance

Serological *surveillance* aims at detecting antibodies against FMDV caused by *infection* or *vaccination* using either, non-structural protein (NSP) tests that detect all FMD types or type-specific tests that detect structural proteins. ~~Positive FMDV antibody test results can have four possible causes:~~

Serological *surveillance* ~~with tests described in the *Terrestrial Manual*~~ is used to:

a) estimate the prevalence or demonstrate the absence of FMDV *infection*/circulation;

b) monitor population immunity.

a) natural *infection* with FMDV;

b) *vaccination* against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).

It may be possible to use sSerum collected for other survey purposes can be used for FMD *surveillance*., provided However, the principles of survey design described in this chapter are met. and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV *infection* is not present in a country, *zone* or *compartment* of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.5.43.45.

Members applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is not practised: additional surveillance procedures

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether or not *vaccination* has been used. In addition to the general conditions described in the above-mentioned articles, a A Member applying for recognition of FMD freedom for the country, or a *zone* or *compartment* where *vaccination* is not practised should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances will be planned and implemented according to general conditions and methods in this chapter, to demonstrate absence of FMDV circulation in previously vaccinated *animals* and absence of FMDV *infection* in non-vaccinated *animals*., during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 8.5.44.46.

Members applying for recognition of freedom from FMD for the whole a country, or a zone or compartment where vaccination is practised: additional surveillance procedures

In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with *vaccination* should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this chapter. Absence of clinical *disease* in the country or *zone* for the past two years should be demonstrated. Furthermore, s*Surveillance* should demonstrate that FMDV has not been circulating in any susceptible populations during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Serological surveys to demonstrate the absence of FMDV circulation should target within vaccinated populations, unvaccinated *animals* or *animals* that are less likely to show vaccine-derived antibodies to NSPs, such as young *animals* vaccinated a limited number of times, or unvaccinated *subpopulations*. Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should be for at least 80 percent of the *animals* in each vaccinated population to have protective immunity. The vaccine must comply with the *Terrestrial Manual*. Evidence to show the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity should be provided.

In designing serosurveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the *animals* have received. The interval between last *vaccination* and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* campaign, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties to the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible *animals* in a given *subpopulation* and in relation to the subset of vaccinated *animals*.

~~Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.~~

~~Evidence to show the effectiveness of the vaccination programme should be provided.~~

Article 8.5.45.~~47~~.

Members re-applying for recognition of freedom from FMD for ~~the whole~~ a country, ~~or a~~ zone or compartment where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

~~In addition to the general conditions described in the above-mentioned articles, a~~A country re-applying for country, ~~or~~ *zone* or *compartment* freedom from FMD where *vaccination* is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection*/circulation. This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising *vaccination*, tests able to detect antibodies to NSPs ~~as described in the *Terrestrial Manual*~~.

~~Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection*/circulation following an *outbreak*:~~

~~1. *slaughter* of all clinically affected and in-contact susceptible *animals*;~~

~~2. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, with subsequent *slaughter* of vaccinated *animals*;~~

~~3. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals*;~~

~~4. vaccination used without *slaughter* of affected *animals* or subsequent *slaughter* of vaccinated *animals*.~~

~~The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.~~

Additional *surveillance* using NSP tests is required to reduce the time period from six to three months in case of *slaughter* of all clinically affected and in-contact susceptible *animals* and *vaccination* of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals* as mentioned in point 1c) of Article 8.5.7. This includes serosurveillance of all *herds* with vaccinated *animals* by sampling all vaccinated ruminants and their non-vaccinated offspring and a representative number of *animals* of other species based on an acceptable level of confidence.

~~In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active *surveillance* programme implemented according to general conditions and methods in this chapter.~~

~~Article 8.5.48.~~

~~**OIE endorsed official control programme for FMD**~~

~~The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD.~~

~~Members may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.~~

~~For a Member's *official control programme* for FMD to be endorsed by the OIE, the Member should:~~

1. ~~submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;~~

2. ~~submit documentation indicating that the *official control programme* for FMD is applicable to the entire territory;~~

3. ~~have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;~~

4. ~~submit a dossier on the epidemiology of FMD in the country describing the following:~~

   a) ~~the general epidemiology in the country highlighting the current knowledge and gaps;~~

   b) ~~the measures to prevent introduction of *infection*;~~

   c) ~~the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;~~

5. ~~submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:~~

   a) ~~the timeline;~~

   b) ~~the performance indicators to assess the efficacy of the control measures to be implemented;~~

6. ~~submit evidence that FMD *surveillance*, taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter, is in place;~~

7. ~~have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual*;~~

8. ~~where vaccination is practised as a part of the *official control programme* for FMD, provide evidence (such as copies of legislation) that vaccination of selected populations is compulsory;~~

9. ~~if applicable, provide detailed information on vaccination campaigns, in particular on:~~

   a) ~~target populations for vaccination;~~

   b) ~~monitoring of vaccination coverage, including serological monitoring of population immunity;~~

   c) ~~technical specification of the vaccines used and description of the licensing procedures in place;~~

   d) ~~the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the *Terrestrial Manual*;~~

~~10. provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.~~

~~The Member's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:~~

- ~~non-compliance with the timelines or performance indicators of the programme; or~~
- ~~significant problems with the performance of the *Veterinary Services*; or~~
- ~~an increase in the incidence of FMD that cannot be addressed by the programme.~~

Article 8.5.46.~~49~~.

The use and interpretation of serological tests (see Figure ~~1~~2)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*. Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used. Where combinations of tests are used, the overall test system performance characteristics should be known. The selection and interpretation of serological tests should be considered in the context of the epidemiological situation.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. ~~Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT).~~ Vaccinated *animals* produce antibodies mainly or entirely to the SP of the virus depending upon vaccine purity. The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. ~~Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests.~~ In unvaccinated populations, SP tests may be used to screen sera for evidence of FMDV *infection*/circulation or to detect the introduction of vaccinated *animals*. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the *vaccination* and can help to identify *infection* since vaccinated-and-infected *animals* may have higher SP antibody titres than vaccinated-only *animals*.

~~In contrast to SP tests,~~ NSP tests can detect antibodies due to *infection*/circulation for ~~to~~ all serotypes of FMD virus regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* insofar as purity is concerned. However, although *a~~A~~nimals* vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, ~~but in some,~~ the ~~titre~~ levels may be lower than ~~that~~ those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with the FMDV have seroconverted it is recommended to take samples for NSP antibody testing not earlier than 30 days after the last case and in any case not earlier than 30 days after the last *vaccination*.

~~Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.~~

~~Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection*/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However,~~

~~NSP antibody tests should be used to monitor for FMDV *infection*/circulation. NSP-ELISAs may be used for screening sera for evidence of *infection*/circulation irrespective of the vaccination status of the *animal*.~~

Positive FMDV antibody test results can have five possible causes:

a) *infection* with FMDV;

b) *vaccination* against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for longer periods);

d) non-specific reactivity of the serum;

e) lack of specificity of the diagnostic tests used.

Procedure in case of positive test results

All seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimize false positive test reactors. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The number and strength of sero reactors should be taken into account.

All *herds* with ~~seropositive~~ at least one *laboratory* confirmed reactor~~s~~ should be investigated immediately. ~~Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection*/circulation for each positive *herd*.~~ The investigation should examine all evidence, including the results of virological tests that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to virus circulation and should document the status of FMDV *infection*/circulation for each positive *herd*. Epidemiological investigation should be continued in parallel.

Clustering of seropositive reactions should be investigated as it may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection*/circulation. As clustering may signal *infection*/circulation, the investigation of all instances must be incorporated in the survey design.

Paired serology can be used to identify virus circulation by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

The investigation should include the reactor *animal(s)*, susceptible *animals* of the same *epidemiological unit* and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)*. The *animals* sampled should remain in the holding pending test results, should be clearly identifiable, accessible and should not be vaccinated during the investigations, so that they can be retested after an adequate period of time. Following clinical examination, a second sample should be taken from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactor(s) after an adequate interval of time has lapsed. If the *animals* are not individually identified, a new serological survey should be carried out in the holding(s) after an adequate period of time, repeating the application of the primary survey design. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and preferably belonging to the same species resident within the initial positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological* unit under investigation for at least two *incubation periods* and should remain serologically negative if virus is not circulating.

~~Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.~~

~~Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.~~

~~1. The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination country or, zone where vaccination is not practised~~

~~Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor *animal* at hand, of susceptible *animals* of the same *epidemiological unit* and of susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal*. If the follow-up investigations provide no evidence FMDV infection, the reactor *animal* shall be classified as FMD negative. In all other cases including the absence of such follow-up investigations, the reactor *animal* should be classified as FMD positive.~~

If circulation is proved then the *outbreak* is declared.

In the absence of FMDV circulation, an *outbreak* can be ruled out, but the significance of FMD positive *animals* is difficult to classify. Such findings can be an indication of acute *infection* followed by recovery or by the development of the carrier state, in ruminants, or due to non-specific reaction or lack of specificity of the diagnostic tests used. Antibodies to NSP may be induced by repeat *vaccination* with vaccines that do not comply with the requirements for purity. However the use of such vaccines is not permissible for countries, *zones* or *compartments* applying for an official status.

In the case of a vaccinated *herd* in a country, *zone* or *compartment* trying to establish or re-establish the status of an FMD free country, *zone* or *compartment* where *vaccination* is practised, the follow-up investigations may be considered completed where the *herd* can be declared free of FMDV circulation. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.

In all other cases, when a small number of FMD positive *animals* are found, at a level consistent with the expected number of non-specific test system findings, it is recommended that such reactor *animals* should be slaughtered, and then the *herd* declared free of FMDV *infection*. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, it is recommended that the *herd* should be slaughtered and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.

~~2. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free country or zone where vaccination is practised status with vaccination~~

~~In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.~~

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

It is suggested that in the primary sampling units where at least one *animal* reacts positive to the NSP test, the following strategy(ies) should be applied:

a) Following clinical examination, a second serum sample should be taken from the *animals* tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of *animals* with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.

   The *animals* sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all *animals* tested are individually identified. These *animals* should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

b) Following clinical examination, serum samples should be collected from representative numbers of susceptible *animals* that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

c) Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.

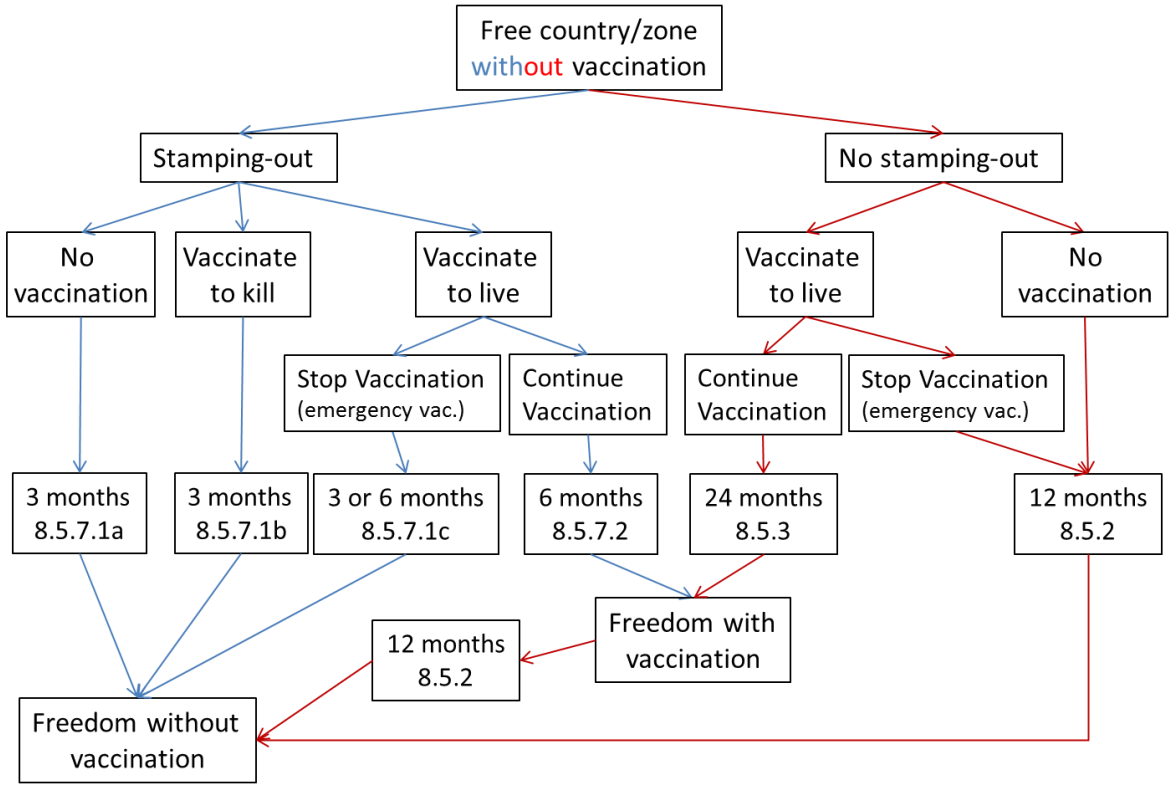
d) Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

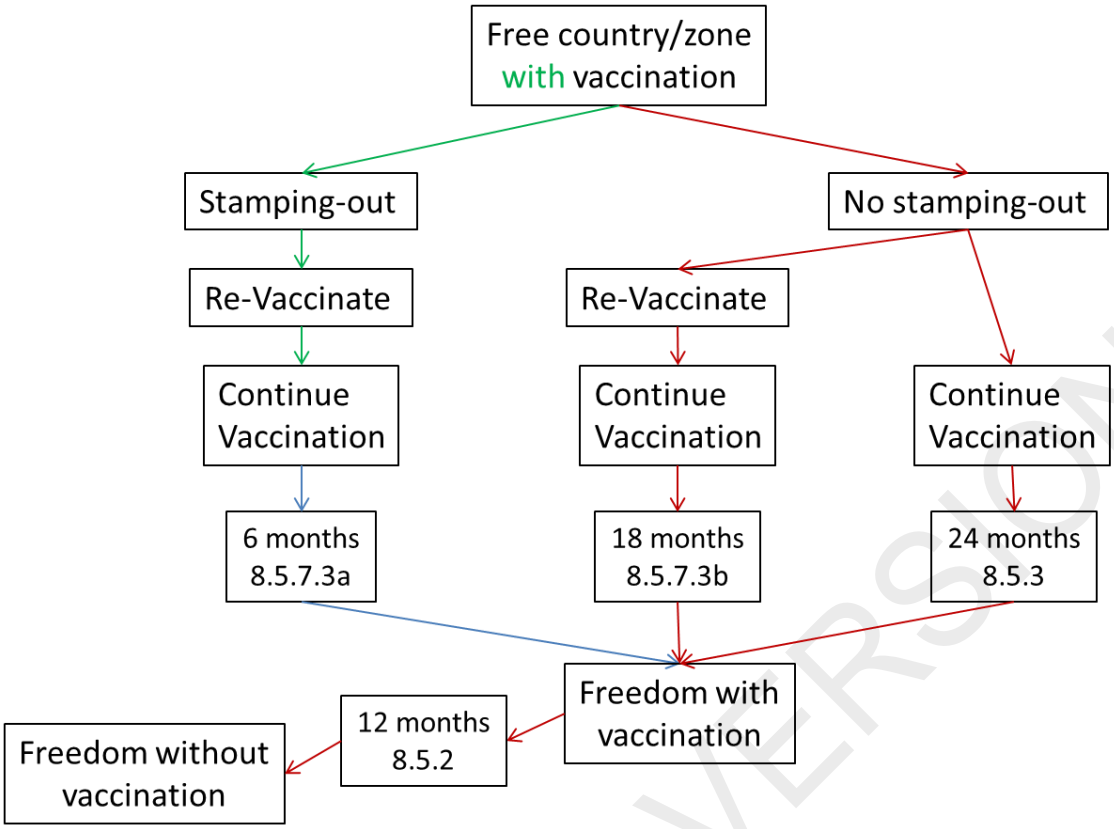
- characterization of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- quantification of *vaccinations* performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;
- control of *animal identification* and movements;
- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

Figure 1: Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status

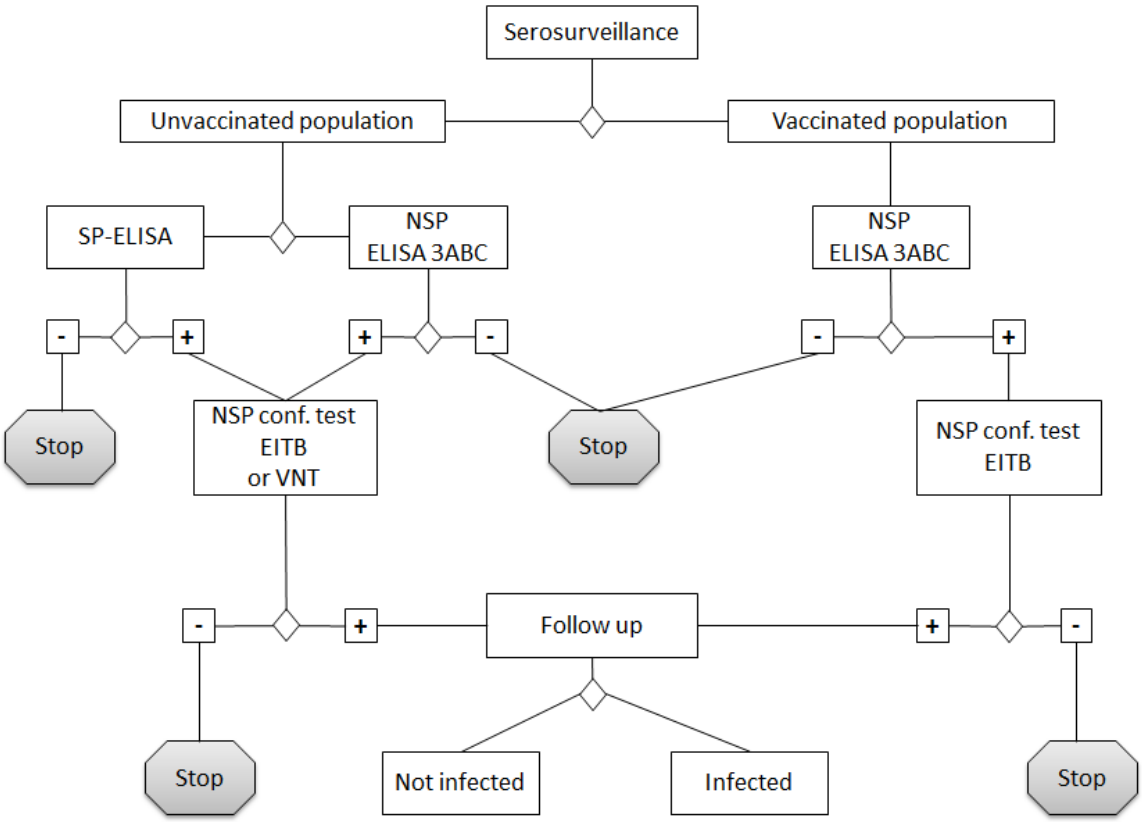


**Waiting periods are minima depending upon outcome of surveillance specified in respective Articles*



**Waiting periods are minima depending upon outcome of surveillance specified in respective Articles*

Figure ~~1~~2: Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys



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CHAPTER 8.5.

INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

Article 8.5.1.

~~**Introduction**~~

1) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla,* and *Camelus bactrianus* with foot and mouth disease virus (FMDV).

2) The following defines the occurrence of FMDV *infection*:

Detection in a sample from an animal listed above, of the virus, viral antigen, nucleic acid or virus-specific antibodies that are not a consequence of *vaccination* by a test as specified in the *Terrestrial Manual*.

3) The following defines the occurrence of FMDV circulation:

Transmission of FMDV, as demonstrated by clinical signs or change in virological or serological status indicative of recent *infection*.

4) For the purposes of the *Terrestrial Code*, the *incubation period* ~~for~~ of FMD shall be 14 days.

5) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with FMDV. Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contact between them. Amongst *Camelidae* only Bactrian camels (*Camelus bactrianus*) are of sufficient susceptibility to have potential for epidemiological significance. South American camelids and dromedaries are not considered of epidemiological importance.

~~For the purposes of this chapter, ruminants include *animals* of the family of Camelidae (except *Camelus dromedarius*).~~

~~For the purposes of this chapter, a *case* is an *animal* infected with FMD virus (FMDV).~~

6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV circulation. FMDV *infection* in ruminants may persist leading to carriers. Although live FMDV can be recovered from carriers, transmission of FMDV from these carriers has not been proven, except from ~~for~~ African buffalo (*Syncerus caffer*).

7) The chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of *infection* with FMDV in the absence of clinical signs.

~~The following defines the occurrence of FMDV *infection:*~~

~~2. FMDV has been isolated and identified as such from an *animal* or a product derived from that *animal*; or;~~

~~2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of FMDV has been identified in samples from one or more *animals*, whether showing clinical signs consistent with FMD or not, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV; or~~

~~3. antibodies to structural or nonstructural proteins of FMDV that are not a consequence of vaccination, have been identified in one or more *animals* showing clinical signs consistent with FMD, or epidemiologically linked to a confirmed or suspected *outbreak* of FMD, or giving cause for suspicion of previous association or contact with FMDV.~~

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

Article 8.5.2.

FMD free country <u>or zone</u> where vaccination is not practised

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.3. should be followed.

Susceptible *animals* in the FMD free country <u>*or zone*</u> where *vaccination* is not practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that effectively prevent the entry of the virus into the free country or *zone*~~,~~. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*.~~,~~ ~~T~~these measures may include a *protection zone*.

To qualify for inclusion in the existing list of FMD free countries or *zones* where *vaccination* is not practised, a Member should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that within the proposed FMD free country or *zone*:

a) there has been no *outbreak* of FMD during the past 12 months;

b) no evidence of FMDV *infection* has been found during the past 12 months;

c) no *vaccination* against FMD has been carried out during the past 12 months;

~~d) no vaccinated *animal* has been introduced since the cessation of vaccination;~~

3) supply documented evidence that for at least the past 12 months:

a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation;

b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

4) describe in detail and supply documented evidence that for at least the past 12 months these are properly implemented and supervised: ~~the boundaries and measures of a *protection zone*, if applicable.~~

a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of the virus into the proposed FMD free country or *zone*;

d) the control of the movement of susceptible *animals* into the proposed FMD free country or *zone* in particular if the procedure described in Articles 8.5.8., 8.5.9. and 8.5.12. are implemented;

e) no vaccinated *animal* has been introduced during the past 12 months except in accordance with Articles 8.5.8. and 8.5.9.

The Member or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is not practiced only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

The status of a country or *zone* will not be affected by applying official emergency *vaccination* in zoological collections in the face of a clearly identifiable FMD threat, provided that the following conditions are met:

a) the zoological collection has a primary purpose to exhibit *animals* or preserve rare species and should be identified in advance, including the boundaries of the facility and be included in the country's contingency plan for FMD;

b) appropriate biosecurity measures are in place, including effective separation from other susceptible domestic populations or *wildlife*;

c) the *animals* are identifiable as belonging to the collection;

d) the vaccine used complies with the *Terrestrial Manual*;

e) *vaccination* is conducted under the supervision of the *Veterinary Authority*;

f) the zoological collection is placed under active clinical *surveillance* for at least 12 months after *vaccination*.

In the event of the application for the status of an FMD free *zone* where *vaccination* is not practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is not practised, it should be indicated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

Article 8.5.3.

FMD free country or zone where vaccination is practised

In defining a *zone* where *vaccination* is practised the principles of Chapter 4.3. should be followed.

Susceptible *animals* in the FMD free country or *zone* where *vaccination* is practised should be protected ~~from neighbouring infected countries~~ by the application of animal health measures that effectively prevent the entry of the virus into the free country or *zone*~~,~~. ~~t~~Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*~~,~~ ~~T~~these measures may include a *protection zone*. Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined *subpopulation* comprised of certain species or other subsets of the total susceptible population.

To qualify for inclusion in the list of FMD free countries or *zones* where *vaccination* is practised, a Member should:

1) have a record of regular and prompt animal *disease* reporting;

2) send a declaration to the OIE stating that within the proposed FMD free country or *zone*:

   a) there has been no *outbreak* of FMD during the past two years;

   b) no evidence of FMDV circulation has been found during the past 12 months;

3) supply documented evidence that:

   a) *surveillance* for FMD and FMDV circulation in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

c) ~~routine~~ compulsory systematic *vaccination* in the target population is carried out ~~for the purpose of the prevention of FMD~~;

d) the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

4) describe in detail and supply documented evidence that these are properly implemented and supervised ~~the boundaries and measures of a *protection zone*, if applicable.~~:

a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;

b) the boundaries and measures of a *protection zone*, if applicable;

c) the system for preventing the entry of the virus into the proposed FMD free country or *zone* (in particular if the procedure described in Article 8.5.8. is implemented);

d) the control of the movement of susceptible *animals* into the proposed FMD free country or *zone*.

The Member or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member that meets the requirements of an FMD free country or *zone* where *vaccination* is practised wishes to change its status to FMD free country or *zone* where *vaccination* is not practised, it should notify the OIE in advance on the intended date of cessation of *vaccination* and apply for the new status within 24 months. The status of this country or *zone* remains unchanged until compliance with Article 8.5.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status will be suspended. If the country does not comply with requirements of Article 8.5.2., evidence should be provided within 3 months that they comply with Article 8.5.3. ~~the status of this country remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred during that period.~~

In the event of the application for the status of an FMD free *zone* where *vaccination* is practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is practised, it should be indicated if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

~~Article 8.5.4.~~

~~**FMD free zone where vaccination is not practised**~~

~~An FMD free *zone* where vaccination is not practised can be established in either an FMD free country where vaccination is practised or in a country of which parts are infected. In defining such a *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* should be protected from the rest of the country and from neighbouring countries if they are of a different *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.~~

To qualify for inclusion in the list of FMD free *zones* where vaccination is not practised, a Member should:

1. have a record of regular and prompt animal *disease* reporting;

2. send a declaration to the OIE stating that within the proposed FMD free *zone*:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV *infection* has been found during the past 12 months;

   c) no vaccination against FMD has been carried out during the past 12 months;

   d) no vaccinated *animal* has been introduced into the *zone* since the cessation of vaccination, except in accordance with Article 8.5.10.;

3. supply documented evidence that:

   a) *surveillance* for FMD and FMDV *infection* in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;

   b) regulatory measures for the early detection, prevention and control of FMD have been implemented;

4. describe in detail and supply documented evidence that these are properly implemented and supervised:

   a) the boundaries of the proposed FMD free *zone*;

   b) the boundaries and measures of a *protection zone*, if applicable;

   c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).;

The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is not practised only after the submitted evidence has been accepted by the OIE.

The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

Article 8.5.5.

FMD free zone where vaccination is practised

An FMD free *zone* where vaccination is practised can be established in either an FMD free country where vaccination is not practised or in a country of which parts are infected. In defining such *zones* the principles of Chapter 4.3. should be followed. Susceptible *animals* in the FMD free *zone* where vaccination is practised should be protected from neighbouring countries or *zones* if they are of a lesser *animal health status* by the application of animal health measures that effectively prevent the entry of the virus, taking into consideration physical or geographical barriers. These measures may include a *protection zone*.

To qualify for inclusion in the list of FMD free *zones* where vaccination is practised, a Member should:

1. have a record of regular and prompt animal *disease* reporting;

2. send a declaration to the OIE that within the proposed FMD free *zone*;

   a) there has been no *outbreak* of FMD for the past two years;

   b) no evidence of FMDV circulation has been found during the past 12 months;

3. supply documented evidence that:

~~a) *surveillance* for FMD and FMDV *infection*/circulation in accordance with Articles 8.5.42. to 8.5.47. and Article 8.5.49. is in operation;~~

~~b) regulatory measures for the early detection, prevention and control of FMD have been implemented;~~

~~c) routine vaccination is carried out for the purpose of the prevention of FMD;~~

~~d) the vaccine used complies with the standards described in the *Terrestrial Manual*;~~

~~4. describe in detail and supply documented evidence that these are properly implemented and supervised:~~

~~a) the boundaries of the proposed FMD free *zone*;~~

~~b) the boundaries and measures of a *protection zone*, if applicable;~~

~~c) the system for preventing the entry of the virus (including the control of the movement of susceptible *animals*) into the proposed FMD free *zone* (in particular if the procedure described in Article 8.5.10. is implemented).~~

~~The proposed free *zone* will be included in the list of FMD free *zones* where vaccination is practised only after the submitted evidence has been accepted by the OIE. The information required in points 2, 3 and 4 b)-c) above should be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3 b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~If a Member that has a *zone* which meets the requirements of a FMD free *zone* where vaccination is practised wishes to change the status of the *zone* to FMD free *zone* where vaccination is not practised, the status of this *zone* remains unchanged for a period of at least 12 months after vaccination has ceased. Evidence should also be provided showing that FMDV *infection* has not occurred in the said *zone* during that period.~~

Article 8.5.4~~6~~.

FMD free compartment

An FMD free *compartment* can be established in either an FMD free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible *animals* in the FMD free *compartment* should be separated from any other susceptible *animals* by the application of an effective biosecurity management system.

A Member wishing to establish an FMD free *compartment* should:

1) have a record of regular and prompt animal *disease* reporting and if not FMD free, have an official control programme and a *surveillance* system for FMD in place according to Articles 8.5.4~~2~~40. to 8.5.4~~7~~42. and Article 8.5.4~~9~~46. that allows ~~an accurate~~ knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;

2) declare for the FMD free *compartment* that:

   a) there has been no *outbreak* of FMD during the past 12 months;

   b) no evidence of FMDV *infection* has been found during the past 12 months;

   c) either: ~~*vaccination* against FMD is prohibited;~~

      i) no *vaccination* against FMD has been carried out during the past 12 months; no vaccinated *animal* has been introduced during the past 12 months; or

      ii) compulsory systematic *vaccination* is carried out and the vaccine used complies with the standards described in the *Terrestrial Manual*, including appropriate vaccine strain selection;

   ~~d) no *animal* vaccinated against FMD within the past 12 months is in the compartment;~~

   d~~e~~) *animals*, semen and embryos should only enter the *compartment* in accordance with relevant articles in this chapter;

e~~f~~) documented evidence shows that *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ is in operation for FMD and FMDV *infection*;

f~~g~~) an *animal identification* and *traceability* system in accordance with Chapters 4.1. and 4.2. is in place;

3) describe in detail:

a) the animal subpopulation in the *compartment*; ~~and~~

b) the biosecurity plan ~~for FMD and FMDV *infection*~~ and, where applicable, the *vaccination* plan, to mitigate the risks identified by the *surveillance* carried out according to point 1 of Article 8.5.4.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no *outbreak* of FMD has occurred within a ten-kilometre radius of ~~the *zone* in which~~ the *compartment* ~~is situated,~~ during the ~~last~~ past three months.

Article 8.5.5 ~~7~~.

FMD infected country or zone

For the purposes of this chapter, when the requirements for acceptance as an FMD free country or *zone* where *vaccination* is not practised or an FMD free country or *zone* where *vaccination* is practised are not fulfilled, such country or *zone* shall be considered as FMD infected. ~~an FMD infected country is a country that does not fulfil the requirements to qualify as either an FMD free country where vaccination is not practised or an FMD free country where vaccination is practised.~~

~~For the purposes of this chapter, an FMD *infected zone* is a *zone* that does not fulfil the requirements to qualify as either an FMD free *zone* where vaccination is not practised or an FMD free *zone* where vaccination is practised.~~

Article 8.5.6 ~~8~~.

Establishment of a containment zone within an FMD free country or zone

In the event of limited *outbreaks* within an FMD free country or *zone*, including within a *protection zone*, with or without *vaccination*, a single *containment zone*, which includes all ~~cases~~ *outbreaks*, can be established for the purpose of minimizing the impact on the entire country or *zone*.

For this to be achieved and for the Member to take full advantage of this process, the *Veterinary Authority* should submit documented evidence as soon as possible to the OIE that:

1) the boundaries of the *containment zone* are established taking into consideration that ~~the *outbreaks* are limited based on the following factors:~~ the *outbreaks* are limited based on the following factors:

a) immediately on suspicion, animal movement control has been imposed in the country or *zone*, and effective controls on the movement of other *commodities* mentioned in this chapter are in place ~~a rapid response including notification has been made~~;

~~b) standstill of animal movements has been imposed, and effective controls on the movement of other *commodities* mentioned in this chapter are in place;~~

~~c~~b) epidemiological investigation (trace-back, trace-forward) is able to demonstrate that the *outbreaks* are epidemiologically related and limited in number and geographic distribution ~~has been completed~~;

~~d) the *infection* has been confirmed~~;

~~e~~c) ~~the primary *outbreak* has been identified, and~~ investigations on the likely source of the *outbreak* have been carried out;

~~f) all *cases* have been shown to be epidemiologically linked;~~

~~g) no new *cases* have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.5.1. after the stamping-out of the last detected *case* is completed;~~

2) a *stamping-out policy*, with or without the use of emergency *vaccination,* has been applied;

3) no new *cases* have been found in the *containment zone* within a minimum of one *incubation period* as defined in Article 8.5.1. after the application of a *stamping-out policy* to the last detected *case*;

~~3.~~4) the susceptible domestic and *captive wild* animal populations within the *containment zone*~~s~~ ~~should~~ are ~~be~~ clearly identifiable as belonging to the *containment zone*;

~~4.~~5) ~~increased passive and targeted~~ *surveillance* in accordance with Articles ~~8.5.42.3 to 8.5.47~~. 8.5.41., 8.5.42. and Article 8.5.~~49~~46. in the *containment zone* and in the rest of the country or *zone* ~~has been carried out~~ is in place ~~and has not detected any evidence of~~ FMDV *infection*;

~~5.~~6) animal health measures that effectively prevent the spread of the FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

~~6. ongoing *surveillance* in the *containment zone* is in place.~~

The free status of the areas outside the *containment zone* ~~would be~~ is suspended ~~pending the establishment of~~ while the *containment zone* is being established. The free status of these areas may ~~could~~ be reinstated irrespective of the provisions of Article 8.5.~~9~~7., once the *containment zone* is clearly established, by complying with points 1 to 6 above. ~~The *containment zone* should be managed in such a way that it can~~ It should be demonstrated that *commodities* for *international trade* ~~can be shown to~~ have originated outside the *containment zone*.

In the event of recurrence of FMDV circulation in the *containment zone,* the approval of the *containment zone* is withdrawn.

The recovery of the FMD free status of the *containment zone* should follow the provisions of Article 8.5.~~9~~7.

Article 8.5.7 ~~9~~.

Recovery of free status (see Figure 1)

1) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is not practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is not practised:

a) three months after the last *case* where a *stamping-out policy* and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.45. and 8.5.~~49~~46.; or

b) three months after the *slaughter* of all vaccinated *animals* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.45. and 8.5.~~49~~46.; or

c) six months after the last *case* or the last *vaccination* (according to the event that occurs the latest), where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated *animals*, and serological *surveillance* are applied in accordance with Articles 8.5.~~42~~40. to 8.5.43., 8.5.~~47~~45. and Article 8.5.~~49~~46., provided that a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of *infection* in the remaining vaccinated population. This period can be reduced to three months if additional *surveillance* in accordance to Article 8.5.45. is carried out.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.5.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. applies.

2) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free country or *zone* where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or *zone* where *vaccination* is practised: 6 months after stamping out of the last *case* where a *stamping-out policy* has been applied and adoption of a continued *vaccination* policy, provided that serological *surveillance* is applied in accordance with Articles 8.5.40. to 8.5.42. and Articles 8.5.44. to 8.5.46, and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of FMDV circulation.

The country or *zone* can gain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.5.2. applies.

~~2.~~3) When an FMD *outbreak* or FMDV ~~*infection*~~ circulation occurs in an FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain the status of FMD free country or *zone* where *vaccination* is practised:

a) 6 months after the last *case* where a *stamping-out policy*, emergency *vaccination* and serological *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.42. and Articles 8.5.44. to 8.5.46~~8.5.45. and Article 8.5.49~~. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation; or

b) 18 months after the last *case* where a *stamping-out policy* is not applied, but emergency *vaccination* and serological *surveillance* in accordance with Articles 8.5.~~42~~40. to 8.5.42. and Articles 8.5.44. to 8.5.46. ~~8.5.47. and Article 8.5.49~~. are applied, provided that the serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence of virus circulation.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.4., has been accepted by the OIE.

~~3.~~4) When an FMD *outbreak* or FMDV *infection* occurs in an FMD free *compartment*, Article 8.5.~~6~~4. applies. The waiting period in point 2a) and 2b) of Article 8.5.4. can be reduced to three months provided that the entire *compartment* has been depopulated, cleansed and disinfected.

5) Members applying for the recovery of status should do so as soon as the respective requirements for the recovery of status are met. When a *containment zone* has been established, the restrictions within the *containment zone* should be lifted in accordance with the requirements of this Article as soon as the *disease* has been successfully eradicated within the *containment zone*.

Article 8.5.8 ~~10~~.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (where vaccination either is or is not practised)

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *infected zone* if transported directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1) no FMD susceptible *animal* has been introduced into the *establishment* of origin and no *animal* in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;

2) the *animals* were kept in the *establishment* of origin for at least three months prior to movement;

3) FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for at least three months prior to movement;

4) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

5) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *infected zone*;

6) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be derived from *animals* that have been subjected to ante- and post-mortem inspection for FMD, with favourable results within 24 hours before and after *slaughter* and treated according to point 2 of Article 8.5.~~25~~22. or Article 8.5.~~26~~23. Other products obtained from the *animals* and any products coming into contact with them should be considered infected, and treated in such a way as to destroy any residual virus in accordance with Articles 8.5.~~34~~31. to 8.5.~~41~~38.

Animals moved into a free *zone* for other purposes should be moved under the supervision of the *Veterinary Authority* and comply with the conditions in Article 8.5.~~14~~12.

Article 8.5.9~~11~~.

Direct ~~T~~ transfer ~~directly to slaughter~~ of FMD susceptible animals from a containment zone for slaughter in ~~to~~ a free zone (where vaccination either is or is not practised) ~~within a country~~

In order not to jeopardise the status of a free *zone*, FMD susceptible *animals* should only leave the *containment zone* if moved by mechanised transport directly to *slaughter* in the nearest designated *abattoir* under the following conditions:

1) the *containment zone* has been officially established according to the requirements in Article 8.5.~~8~~6.;

2) the *animals* should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *abattoir* without coming into contact with other susceptible *animals*;

3) such an *abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of *animals* from the *containment zone*;

4) *vehicles* and the *abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The *meat* should be derived from *animals* that have been subjected to ante- and post-mortem inspection for FMD, with favourable results within 24 hours before and after *slaughter* and treated according to point 2 of Article 8.5.~~25~~22. or Article 8.5.~~26~~23. Other products obtained from the *animals* and any products coming into contact with them should be treated in such a way as to destroy any residual virus in accordance with Articles 8.5.~~34~~31. to 8.5.~~41~~38.

Article 8.5.10.~~12~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of FMD on the day of shipment;

2) were kept since birth or for at least the past three months in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised; ~~or a FMD free *compartment*~~

3) have not been vaccinated;

4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*~~.~~;

Article 8.5.11.~~13~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the *animals*:

1) showed no clinical sign of FMD on the day of shipment;

2) were kept in an FMD free country, ~~or~~ *zone or compartment* where *vaccination* is practised, since birth or for at least the past three months; ~~and~~

3) when destined to an FMD free country or *zone* where *vaccination* is not practised, have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus ~~when destined to an FMD free country or *zone* where vaccination is not practised~~;

4) if transiting an *infected zone*, were not exposed to any source of FMD *infection* during transportation to the *place of shipment*.

Article 8.5. 12.~~14~~.

Recommendations for importation from FMD infected countries or zones

For domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that ~~the *animals*~~:

1) the *animals* showed no clinical sign of FMD on the day of shipment;

2) prior to isolation, the *animals* were kept in the *establishment* of origin ~~since birth, or~~

   a) for ~~the past~~ 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is in force in the *exporting country*, or

   b) for ~~the past~~ 3 months, or since birth if younger than three months, if a *stamping-out policy* is not in force in the *exporting country*,

3) ~~and that~~ FMD has not occurred within a ten-kilometre radius of the *establishment* of origin for the relevant period as defined in points 2 a) and b) above;

~~3~~4) the *animals* were isolated in an *establishment* or a *quarantine station* for the 30 days prior to shipment, and all *animals* in isolation were subjected to diagnostic tests (virus detection on a probang sample in ruminants or on throat swabs in pigs and serology) for evidence of FMDV *infection* with negative results on samples collected at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *establishment* or a *quarantine station* during that period; ~~or~~

4) ~~were kept in a *quarantine station* for the 30 days prior to shipment, all *animals* in quarantine were subjected to diagnostic tests (probang and serology) for evidence of FMDV *infection* with negative results at the end of that period, and that FMD did not occur within a ten-kilometre radius of the *quarantine station* during that period;~~

5) the *animals* were not exposed to any source of FMD *infection* during their transportation from the *establishment* or *quarantine station* to the *place of shipment*.

Article 8.5. 13.~~15~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For fresh semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

   c) were kept in an *artificial insemination centre* where none of the *animals* had a history of *infection*;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.14.~~16~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

Article 8.5.15.~~17~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept for at least three months prior to collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is practised;

   ~~c) if destined to an FMD free country or *zone* where vaccination is not practised:~~

   ~~i)~~c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

   ~~ii)~~d) had been vaccinated at least twice, with the last *vaccination* not more than 12 and not less than one month prior to collection;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

2~~3~~) the semen:

   a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

   b) was stored in the country of origin for a period of at least one month following collection, and during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.16~~18~~.

Recommendations for importation from FMD infected countries or zones

For frozen semen of domestic ruminants and pigs

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor *animals*:

   a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;

   b) were kept in an ~~*establishment*~~ *artificial insemination centre* where no *animal* had been added in the 30 days before collection, and that FMD has not occurred within 10 kilometres for the 30 days before and after collection;

   c) have not been vaccinated and were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMD virus, with negative results; or

   d) had been vaccinated at least twice, with the last *vaccination* not more than 12 and not less than one month prior to collection;

~~2. no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection;~~

~~3~~.2) the semen:

a) was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.;

b) was subjected, with negative results, to a test for FMDV ~~*infection*~~ if the donor *animal* has been vaccinated within the 12 months prior to collection;

c) was stored in the country of origin for a period of at least one month following collection, and that during this period no *animal* on the *establishment* where the donor *animals* were kept showed any sign of FMD.

Article 8.5.17.~~19.~~

Recommendations for the importation of *in vivo* derived embryos of cattle

Irrespective of the FMD status of the *exporting country*, *zone* or *compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in conformity with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.5.18.~~20.~~

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

a) showed no clinical sign of FMD at the time of collection of the oocytes;

b) were kept for at least three months prior to ~~at the time of~~ collection in an FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~;

2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.5.~~15~~13., 8.5.~~16~~14., 8.5.~~17~~15. or 8.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.19.~~21~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For *in vitro* produced embryos of cattle

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

   a) showed no clinical sign of FMD at the time of collection of the oocytes;

   b) were kept for at least three months prior to collection in an FMD free country, or *zones* or *compartments* where *vaccination* is practised;

   ~~c) if destined for an FMD free country or *zone* where vaccination is not practised or a FMD free *compartment*:~~

   ~~i)~~c) have not been vaccinated and were subjected, with negative results, to tests for antibodies against FMD virus; or

   ~~ii)~~d) had been vaccinated at least twice, with the last *vaccination* not less than one month and not more than 12 months prior to collection;

~~2) no other *animal* present in the *artificial insemination centre* has been vaccinated within the month prior to collection~~;

2) fertilization was achieved with semen meeting the conditions referred to in Articles 8.5.~~15~~13., 8.5.~~16~~14., 8.5.~~17~~15. or 8.5.~~18~~16., as relevant;

3) the oocytes were collected, and the embryos were processed and stored in conformity with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.5.20.~~22~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is not practised ~~or FMD free compartments~~

For fresh meat or meat products of FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1) have been kept in the FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is not practised ~~or a FMD free *compartment*~~, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.;

2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.

Article 8.5. 21.~~23~~.

Recommendations for importation from FMD free countries, ~~or~~ zones or compartments where vaccination is practised

For fresh meat and meat products of ruminants and pigs ~~cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:

1) have been kept in the FMD free country, ~~or~~ *zone* or *compartment* where *vaccination* is practised, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.;

2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results~~.~~;

3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, have been removed.

~~Article 8.5.24.~~

~~**Recommendations for importation from FMD free countries or zones where vaccination is practiced**~~

~~For fresh meat or meat products of pigs and ruminants other than cattle and buffaloes~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from *animals* which:~~

~~1) have been kept in the FMD free country or *zone* where vaccination is practised, or which have been imported in accordance with Article 8.5.12., Article 8.5.13. or Article 8.5.14.;~~

~~2) have been slaughtered in an approved *abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results.~~

Article 8.5.22.~~25~~.

Recommendations for importation from FMD infected countries or zones, where an official control programme for FMD, involving compulsory systematic vaccination ~~of cattle,~~ exists

For fresh meat of cattle and buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat*:

1) comes from *animals* which:

   a) have remained in the *exporting country* for at least three months prior to *slaughter*;

   b) have remained, during this period, in a part of the country where cattle and buffaloes are regularly vaccinated against FMD and where official controls are in operation;

   c) have been vaccinated at least twice with the last *vaccination* not more than 12 months and not less than one month prior to *slaughter*;

   d) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a ten-kilometre radius of the *establishment* during that period;

   e) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and buffaloes were loaded, directly from the *establishment* of origin to the approved *abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;

   f) have been slaughtered in an approved *abattoir*:

      i) which is officially designated for export;

      ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;

   g) have been subjected to ante- and post-mortem inspections for FMD with favourable results within 24 hours before and after *slaughter*;

2) comes from deboned carcasses:

   a) from which the major lymphatic nodes have been removed;

   b) which, prior to deboning, have been submitted to maturation at a temperature above + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below 6.0 when tested in the middle of both the longissimus dorsi.

Article 8.5.23.~~26~~.

Recommendations for importation from FMD infected countries or zones

For meat products of ~~domestic ruminants and pigs~~ FMD susceptible animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the entire consignment of *meat* comes from *animals* which have been slaughtered in an *approved abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;

2) the *meat* has been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.~~34~~31.;

3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMD virus.

Article 8.5.24.~~27~~.

Recommendations for importation from FMD free countries~~,~~ ~~or~~ zones or compartments ~~(where vaccination either is or is not practised)~~ ~~or FMD free compartments~~

For milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products come from *animals* which have been kept in an FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.5.~~12~~10., Article 8.5.~~13~~11. or Article 8.5.~~14~~12.

Article 8.5.25.~~28~~.

Recommendations for importation from FMD infected countries or zones where an official control programme exists

For milk, cream, milk powder and milk products

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products:

   a) originate from *establishments* ~~*herds or flocks*~~ which were not infected or suspected of being infected with FMD at the time of *milk* collection;

   b) have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Article 8.5.~~38~~35. and in Article 8.5.~~39~~36.;

2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMD virus.

Article 8.5.26.~~29~~.

Recommendations for importation from FMD infected countries

For blood and meat-meals from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 8.5.27.~~30~~.

Recommendations for importation from FMD infected countries

For wool, hair, bristles, raw hides and skins from FMD susceptible animals ~~(from domestic or wild ruminants and pigs)~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) these products have been processed to ensure the destruction of the FMD virus in conformity with one of the procedures referred to in Articles 8.5.~~35~~32., 8.5.~~36~~33. and 8.5.~~37~~34.;

2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMD virus.

Veterinary Authorities can authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather – e.g. wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.5.28.~~31~~.

Recommendations for importation from FMD infected countries or zones

For straw and forage

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these *commodities*:

1) are free of grossly identifiable contamination with material of animal origin;

2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:

   a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten minutes,

   b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;

OR

3) have been kept in bond for at least three months (under study) before being released for export.

Article 8.5.29.~~32~~.

Recommendations for importation from FMD free countries or zones (where vaccination either is or is not practised)

For skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products are derived from *animals* that have been killed in such a country or *zone*, or which have been imported from a country or *zone* free of FMD (where *vaccination* either is or is not practised).

Article 8.5.30.~~33~~.

Recommendations for importation from FMD infected countries or zones

For skins and trophies derived from FMD susceptible wild animals

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of the FMD virus in conformity with the procedures referred to in Article 8.5.~~40~~37.

Article 8.5.31.~~34~~.

Procedures for the inactivation of the FMD virus in meat and meat products

For the inactivation of viruses present in *meat* and *meat products*, one of the following procedures should be used:

1. Canning

   Meat and *meat products* ~~is~~ are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate the FMD virus.

2. Thorough cooking

   Meat, previously deboned and defatted, and *meat products* shall be subjected to heating so that an internal temperature of 70°C or greater is maintained for a minimum of 30 minutes.

   After cooking, ~~it~~ they shall be packed and handled in such a way that it cannot be exposed to a source of virus.

3. Drying after salting

   When *rigor mortis* is complete, the *meat* must be deboned, salted with cooking salt (NaCl) and completely dried. It must not deteriorate at ambient temperature.

   'Drying' is defined in terms of the ratio between water and protein which must not be greater than 2.25:1.

Article 8.5.32.~~35~~.

Procedures for the inactivation of the FMD virus in wool and hair

For the inactivation of viruses present in wool and hair for industrial use, one of the following procedures should be used:

1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);

2) chemical depilation by means of slaked lime or sodium sulphide;

3) fumigation in formaldehyde in a hermetically sealed chamber for at least 24 hours. The most practical method is to place potassium permanganate in containers (which must NOT be made of plastic or polyethylene) and add commercial formalin; the amounts of formalin and potassium permanganate are respectively 53 ml and 35 g per cubic metre of the chamber;

4) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;

5) storage of wool at ~~18°C for four weeks, or~~ 4°C for four months, 18°C for four weeks or 37°C for eight days.

Article 8.5.33.~~36~~.

Procedures for the inactivation of the FMD virus in bristles

For the inactivation of viruses present in bristles for industrial use, one of the following procedures should be used:

1) boiling for at least one hour;

2) immersion for at least 24 hours in a 1 percent solution of formaldehyde prepared from 30 ml commercial formalin per litre of water.

Article 8.5.34.~~37~~.

Procedures for the inactivation of the FMD virus in raw hides and skins

For the inactivation of viruses present in raw hides and skins for industrial use, the following procedure should be used: salting for at least 28 days in sea salt containing 2 percent sodium carbonate.

Article 8.5.35.~~38~~.

Procedures for the inactivation of the FMD virus in milk and cream for human consumption

For the inactivation of viruses present in *milk* and cream for human consumption, one of the following procedures should be used:

1) a sterilisation process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or

2) if the milk has a pH less than 7.0, a sterilisation process applying a minimum temperature of 72°C for at least 15 seconds (high temperature – short time pasteurisation [HTST]), or

3) if the milk has a pH of 7.0 or over, the HTST process applied twice.

Article 8.5.36.~~39~~.

Procedures for the inactivation of the FMD virus in milk for animal consumption

For the inactivation of viruses present in *milk* for animal consumption, one of the following procedures should be used:

1) the HTST process applied twice;

2) HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with dessication;

3) UHT combined with another physical treatment referred to in point 2 above.

Article 8.5.37~~40~~.

Procedures for the inactivation of the FMD virus in skins and trophies from wild animals susceptible to the disease

For the inactivation of viruses present in skins and trophies from *wild animals* susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed;

2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher);

3) soaking, with agitation, in a 4 percent (w/v) solution of washing soda (sodium carbonate – Na_2CO_3) maintained at pH 11.5 or above for at least 48 hours;

4) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained at below pH 3.0 for at least 48 hours; wetting and dressing agents may be added;

5) in the case of raw hides, salting for at least 28 days with sea salt containing 2 percent washing soda (sodium carbonate – Na_2CO_3).

Article 8.5.38.~~41~~.

Procedures for the inactivation of the FMD virus in casings of ruminants and pigs

For the inactivation of viruses present in casings of ruminants and pigs, the following procedures should be used: salting for at least 30 days either with dry salt (NaCl) or with saturated brine (NaCl, ~~Aw~~ a_w< 0.80), or with phosphate supplemented ~~dry~~ salt containing 86.5 percent NaCl, 10.7 percent Na_2HPO_4 and 2.8 percent Na_3PO_4 (weight/weight/weight), either dry or as a saturated brine (a_w< 0.80), and kept at a temperature of greater than 12°C during this entire period.

Article 8.5.39.

OIE endorsed official control programme for FMD

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD. The *official control programme* should be applicable to the entire country even if certain measures are directed towards defined *subpopulations*.

Members may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.

For a Member's *official control programme* for FMD to be endorsed by the OIE, the Member should:

1) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;

2) submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;

3) submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:

   a) the timeline;

   b) the performance indicators to assess the efficacy of the control measures to be implemented;

   c) submit documentation indicating that the *official control programme* for FMD is applicable to the entire country;

4) submit a dossier on the epidemiology of FMD in the country describing the following:

   a) the general epidemiology in the country highlighting the current knowledge and gaps;

   b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate virus circulation in domestic ruminants in at least one *zone* in the country;

   c) the main livestock production systems and movement patterns of FMD susceptible *animals* and their products within and into the country;

5) submit evidence that FMD *surveillance* is in place:

a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;

b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;

6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:

a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;

b) detailed information on *vaccination* campaigns, in particular on:

i) target populations for *vaccination*;

ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;

iii) technical specification of the vaccines used and description of the licensing procedures in place;

iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;

7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.

The Member's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

– non-compliance with the timelines or performance indicators of the programme; or

– significant problems with the performance of the *Veterinary Services*; or

– an increase in the incidence of FMD that cannot be addressed by the programme.

Article 8.5.40.~~42~~.

Surveillance: introduction

Articles 8.5.~~42~~40. to 8.5.~~47~~46. ~~and Article 8.5.49.~~ define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Members seeking establishment, maintenance and recovery of freedom from FMD at the country, *zone* or *compartment* level, either with or without the use of *vaccination* and Members seeking endorsement of their *official control programme* for FMD, in accordance with Article 8.5.39. *Surveillance* aimed at identifying *disease* and *infection*/virus circulation should cover all the susceptible species, including *wildlife*, if applicable, within the country, *zone* or *compartment*. ~~Guidance is provided for Members seeking reestablishment of freedom from FMD for the entire country or for a *zone*, either with or without vaccination, or a *compartment*, following an *outbreak* and for the maintenance of FMD status.~~

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is ~~impossible~~ inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an *outbreak* caused by a pig-adapted strain of ~~FMD virus (~~FMDV~~)~~ should differ significantly from an application

designed to prove freedom from FMD for a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*. *Surveillance* strategies employed for establishing and maintaining a *compartment* should also identify the prevalence, distribution and characteristics of FMD outside the *compartment* in the country or *zone. Surveillance* strategies employed in support of an OIE endorsed *official control programme* should show evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*. There is therefore considerable latitude available to Members to design and implement *surveillance* on the one hand to establish that the whole territory or part of it is free from FMDV *infection*/circulation and on the other to understand the epidemiology of FMD as part of the official FMD control programmes.

It is incumbent upon the Member to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are identified and managed. This should include provision of scientifically based supporting data. ~~There is therefore considerable latitude available to Members to provide a well-reasoned argument to prove that the absence of FMDV *infection* (in non-vaccinated populations) or circulation (in vaccinated populations) is assured at an acceptable level of confidence.~~

Surveillance for FMD should be in the form of a continuing programme. The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.

The strategy employed to establish the prevalence of FMDV *infection* or to demonstrate the absence of FMDV *infection*/circulation may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be an appropriate strategy. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). The Member should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination/infection* history and production class of *animals* in the target population.

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether or not they are indicative of *infection*/circulation. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* as well as *herds* which may be epidemiologically linked to it.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

– characterization of the existing production systems;

– results of clinical *surveillance* of the suspects and their cohorts;

– quantification of *vaccinations* performed on the affected sites;

– sanitary protocol and history of the *establishments* with positive reactors;

– control of *animal identification* and movements;

– other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

~~*Surveillance* for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it is free from FMDV *infection*/circulation.~~

~~For the purposes of this chapter, virus circulation means transmission of FMDV as demonstrated by clinical signs, serological evidence or virus isolation.~~

Article 8.5.41.~~43~~.

Surveillance: ~~**general conditions and methods**~~ **general principles**

1) A *surveillance* system in accordance with Chapter 1.4. should be ~~under~~ the responsibility of the *Veterinary Authority*. A procedure should be in place for the rapid collection and transport of samples ~~from suspect *cases* of FMD~~ to a *laboratory* for FMD diagnose~~i~~s ~~as described in the *Terrestrial Manual*~~. This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.

2) The FMD *surveillance* programme should:

   a) include structured non-random *surveillance* activities as described in Article 1.4.5. with particular reference to an early warning system throughout the production, marketing and processing chain for reporting ~~suspicious~~ suspect *cases*. Farmers and workers who have day-to-day contact with livestock, as well as diagnosticians, should report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private *veterinarians* or *veterinary para-professionals*) by government information programmes and the *Veterinary Authority*. All suspect *cases* of FMD should be investigated immediately. ~~Where suspicion cannot be resolved by epidemiological and clinical investigation, s~~Samples should be taken and submitted for diagnostic testing ~~a *laboratory*~~, unless the suspect *case* can be confirmed or ruled out by epidemiological and clinical investigation. ~~This requires that sampling kits and other equipment are available for those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for assistance from a team with expertise in FMD diagnosis and control.~~ Any *epidemiological unit* within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced;

   ~~b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of *animals*, such as those adjacent to an FMD infected country or *infected zone* (for example, bordering a game park in which infected *wildlife* are present).~~

   b) implement structured population-based surveys, when appropriate, as described in Article 1.4.4.

3) The *surveillance* programme above should:

   a) identify the nature of risk factors, including the role of *wildlife*, to inform targeted *surveillance* strategies when appropriate;

   b) implement, when relevant, an appropriate combination of clinical investigation and other diagnostic procedures in high risk groups.

~~3~~4) An effective *surveillance* system should ~~will~~ periodically identify ~~suspicious~~ suspect *cases* that require follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Details of the occurrence of suspect *cases* and how they were investigated and dealt with should be documented. ~~The rate at which such suspicious *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably~~. ~~Applications for freedom from FMDV *infection*/circulation should, in consequence, provide details of the occurrence of suspicious *cases* and how they were investigated and dealt with~~. This should include the results of diagnostic ~~*laboratory*~~ testing and the control measures to which the *animals* concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

Article 8.5.42.~~44~~.

Surveillance: methods ~~strategies~~

~~1. Introduction~~

~~The target population for *surveillance* aimed at identifying *disease* and *infection* should cover all the susceptible species within the country, *zone* or *compartment*.~~

~~The design of *surveillance* programmes to prove the absence of FMDV *infection*/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.~~

~~The strategy employed may be based on randomised sampling requiring *surveillance* consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. The Member should justify the *surveillance* strategy chosen as adequate to detect the presence of FMDV *infection*/circulation in accordance with Chapter 1.4. and the epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member wishes to apply for recognition of a specific *zone* within the country as being free from FMDV *infection*/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the *zone*.~~

~~For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect *infection*/circulation if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member must justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.~~

~~Irrespective of the survey design selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/*infection* history and production class of *animals* in the target population.~~

~~Irrespective of the testing system employed, *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following-up positives to ultimately determine with a high level of confidence, whether they are indicative of *infection*/circulation or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as *herds* which may be epidemiologically linked to it.~~

1~~2~~. Clinical surveillance

The detection of clinical signs by farmers, *veterinary para-professionals* and *veterinarians* is the foundation of an early warning system and of clinical *surveillance*. Clinical *surveillance* ~~aims at detecting clinical signs of FMD by~~ requires close physical examination of susceptible *animals*. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated~~.~~ . ~~It may~~ as it can ~~be able to~~ provide a high level of confidence of detection of *disease* if a sufficient~~ly large~~ number of clinically susceptible *animals* is examined at an appropriate frequency.

Clinical *surveillance* and ~~*laboratory*~~ diagnostic testing should ~~always~~ be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. ~~*Laboratory*~~ Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive ~~serology~~ laboratory tests. ~~Any sampling unit within which suspicious *animals* are detected should be classified as infected until contrary evidence is produced.~~ Clinical *surveillance* may be insufficient in case of species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such cases, sero-surveillance should be used.

~~A number of issues must be considered in clinical *surveillance* for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.~~

~~Identification of clinical *cases* is fundamental to FMD *surveillance*. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such *animals*. It is essential that FMDV isolates are sent regularly to the regional reference *laboratory* for genetic and antigenic characterization.~~

~~3~~2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide materials. It is essential that FMDV isolates are sent regularly to an OIE Reference Laboratory.

Virological *surveillance* ~~using tests described in the *Terrestrial Manual* should be conducted~~ aims to:

~~a)~~ ~~to monitor at risk populations;~~

~~b)~~a) ~~to~~ confirm clinically suspect *cases*;

~~c~~b) ~~to~~ follow up positive serological results;

c) characterize isolates for epidemiological studies and vaccine matching;

~~d) to test 'normal' daily mortality, to ensure early detection of *infection* in the face of vaccination or in *establishments* epidemiologically linked to an *outbreak*.~~

d) monitor at risk populations.

~~4~~3. Serological surveillance

Serological *surveillance* aims at detecting antibodies against FMDV caused by *infection* or *vaccination* using either, non-structural protein (NSP) tests that detect all FMD types or type-specific tests that detect structural proteins. ~~Positive FMDV antibody test results can have four possible causes:~~

Serological *surveillance* ~~with tests described in the *Terrestrial Manual*~~ is used to:

a) estimate the prevalence or demonstrate the absence of FMDV *infection*/circulation;

b) monitor population immunity.

~~a)~~ ~~natural *infection* with FMDV;~~

~~b)~~ ~~*vaccination* against FMD;~~

~~c)~~ ~~maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);~~

~~d)~~ ~~heterophile (cross) reactions.~~

~~It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on nonstructural viral proteins – see below).~~

~~It may be possible to use s~~Serum collected for other ~~survey~~ purposes can be used for FMD *surveillance*~~.~~, provided ~~However,~~ the principles of survey design described in this chapter are met. ~~and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.~~

~~The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain *infection*. As clustering may signal field strain *infection*, the investigation of all instances must be incorporated in the survey design. If *vaccination* cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to nonstructural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.~~

The results of random or targeted serological surveys are important in providing reliable evidence ~~that FMDV *infection* is not present in a country, *zone* or *compartment*~~ of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.5.43.~~45~~.

Members applying for recognition of freedom from FMD for ~~the whole~~ a country~~, or a~~ zone or compartment where vaccination is not practised: additional surveillance procedures

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether or not *vaccination* has been used. ~~In addition to the general conditions described in the above-mentioned articles, a~~ A Member applying for recognition of FMD freedom for the country, ~~or a~~ *zone* or *compartment* where *vaccination* is not practised should ~~provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances will be planned and implemented according to general conditions and methods in this chapter, to~~ demonstrate absence of FMDV circulation in previously vaccinated *animals* and absence of FMDV *infection* in non-vaccinated *animals*~~., during the preceding 12 months in susceptible populations. This requires the support of a national or other *laboratory* able to undertake identification of FMDV *infection* through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.~~

Article 8.5.44.~~46~~.

Members applying for recognition of freedom from FMD for ~~the whole~~ a country~~, or a~~ zone or compartment where vaccination is practised: additional surveillance procedures

~~In addition to the general conditions described in the above-mentioned articles, a Member applying for recognition of country or *zone* freedom from FMD with *vaccination* should show evidence of an effective *surveillance* programme planned and implemented according to general conditions and methods in this chapter. Absence of clinical *disease* in the country or *zone* for the past two years should be demonstrated. Furthermore, s~~*Surveillance* should demonstrate that FMDV has not been circulating in any susceptible population~~s~~ during the past 12 months. This will require serological *surveillance* incorporating tests able to detect antibodies to NSPs ~~as described in the *Terrestrial Manual*~~. Serological surveys to demonstrate the absence of FMDV circulation should target within vaccinated populations, unvaccinated *animals* or *animals* that are less likely to show vaccine-derived antibodies to NSPs, such as young *animals* vaccinated a limited number of times, or unvaccinated *subpopulations*. ~~Vaccination to prevent the transmission of FMDV may be part of a disease control programme. The level of *herd* immunity required to prevent transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. However, the aim should be for at least 80 percent of the *animals* in each vaccinated population to have protective immunity. The vaccine must comply with the *Terrestrial Manual*.~~ Evidence to show the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity should be provided.

In designing serosurveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the *animals* have received. The interval between last *vaccination* and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* campaign, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties to the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible *animals* in a given *subpopulation* and in relation to the subset of vaccinated *animals*.

~~Based on the epidemiology of FMD in the country or *zone*, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case, the rationale should be contained within the dossier accompanying the application to the OIE for recognition of status.~~

~~Evidence to show the effectiveness of the vaccination programme should be provided.~~

Article 8.5.~~45.~~47.

Members re-applying for recognition of freedom from FMD for ~~the whole~~ a country~~, or a zone or compartment~~ where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures

~~In addition to the general conditions described in the above-mentioned articles, a~~A country re-applying for country~~, or~~ *zone* or *compartment* freedom from FMD where *vaccination* is practised or not practised should show evidence of an active *surveillance* programme for FMD as well as absence of FMDV *infection*/circulation. This will require serological *surveillance* incorporating, in the case of a country or a *zone* practising *vaccination*, tests able to detect antibodies to NSPs ~~as described in the *Terrestrial Manual*~~.

~~Four strategies are recognised by the OIE in a programme to eradicate FMDV *infection*/circulation following an *outbreak*:~~

~~1. *slaughter* of all clinically affected and in-contact susceptible *animals*;~~

~~2. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, with subsequent *slaughter* of vaccinated *animals*;~~

~~3. *slaughter* of all clinically affected and in-contact susceptible *animals* and vaccination of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals*;~~

~~4. vaccination used without *slaughter* of affected *animals* or subsequent *slaughter* of vaccinated *animals*.~~

~~The time periods before which an application can be made for re-instatement of freedom from FMD depends on which of these alternatives is followed. The time periods are prescribed in Article 8.5.9.~~

Additional *surveillance* using NSP tests is required to reduce the time period from six to three months in case of *slaughter* of all clinically affected and in-contact susceptible *animals* and *vaccination* of at-risk *animals*, without subsequent *slaughter* of vaccinated *animals* as mentioned in point 1c) of Article 8.5.7. This includes serosurveillance of all *herds* with vaccinated *animals* by sampling all vaccinated ruminants and their non-vaccinated offspring and a representative number of *animals* of other species based on an acceptable level of confidence.

~~In all circumstances, a Member re-applying for country or *zone* freedom from FMD with vaccination or without vaccination should report the results of an active *surveillance* programme implemented according to general conditions and methods in this chapter.~~

~~Article 8.5.48.~~

~~**OIE endorsed official control programme for FMD**~~

~~The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain free status for FMD.~~

~~Members may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.~~

~~For a Member's *official control programme* for FMD to be endorsed by the OIE, the Member should:~~

1. ~~submit documented evidence on the capacity of the *Veterinary Services* to control FMD; this evidence can be provided by countries following the OIE PVS Pathway;~~

2. ~~submit documentation indicating that the *official control programme* for FMD is applicable to the entire territory;~~

3. ~~have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;~~

4. ~~submit a dossier on the epidemiology of FMD in the country describing the following:~~

   a) ~~the general epidemiology in the country highlighting the current knowledge and gaps;~~

   b) ~~the measures to prevent introduction of *infection*;~~

   c) ~~the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;~~

5. ~~submit a detailed plan on the programme to control and eventually eradicate FMD in the country or *zone* including:~~

   a) ~~the timeline;~~

   b) ~~the performance indicators to assess the efficacy of the control measures to be implemented;~~

6. ~~submit evidence that FMD *surveillance*, taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter, is in place;~~

7. ~~have diagnostic capability and procedures, including regular submission of samples to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the *Terrestrial Manual*;~~

8. ~~where vaccination is practised as a part of the *official control programme* for FMD, provide evidence (such as copies of legislation) that vaccination of selected populations is compulsory;~~

9. ~~if applicable, provide detailed information on vaccination campaigns, in particular on:~~

   a) ~~target populations for vaccination;~~

   b) ~~monitoring of vaccination coverage, including serological monitoring of population immunity;~~

   c) ~~technical specification of the vaccines used and description of the licensing procedures in place;~~

   d) ~~the proposed timeline for the transition to the use of vaccines, fully compliant with the standards and methods described in the *Terrestrial Manual*;~~

~~10. provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.~~

~~The Member's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.~~

~~The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:~~

- ~~non-compliance with the timelines or performance indicators of the programme; or~~
- ~~significant problems with the performance of the *Veterinary Services*; or~~
- ~~an increase in the incidence of FMD that cannot be addressed by the programme.~~

Article 8.5.46.~~49~~.

The use and interpretation of serological tests (see Figure ~~1~~2)

The recommended serological tests for FMD *surveillance* are described in the *Terrestrial Manual*. Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used. Where combinations of tests are used, the overall test system performance characteristics should be known. The selection and interpretation of serological tests should be considered in the context of the epidemiological situation.

Animals infected with FMDV produce antibodies to both the structural proteins (SP) and the nonstructural proteins (NSP) of the virus. ~~Tests for SP antibodies to include SP-ELISAs and the virus neutralisation test (VNT).~~ Vaccinated *animals* produce antibodies mainly or entirely to the SP of the virus depending upon vaccine purity. The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. ~~Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests.~~ In unvaccinated populations, SP tests may be used to screen sera for evidence of FMDV *infection*/circulation or to detect the introduction of vaccinated *animals*. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the *vaccination* and can help to identify *infection* since vaccinated-and-infected *animals* may have higher SP antibody titres than vaccinated-only *animals*.

~~In contrast to SP tests,~~ NSP tests can detect antibodies due to *infection*/circulation for ~~to~~ all serotypes of FMD virus regardless of the *vaccination* status of the *animals* provided the vaccines comply with the standards of the *Terrestrial Manual* insofar as purity is concerned. However, although *a~~A~~nimals* vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, ~~but in some,~~ the ~~titre~~ levels may be lower than ~~that~~ those found in infected *animals* that have not been vaccinated. To ensure that all *animals* that had contact with the FMDV have seroconverted it is recommended to take samples for NSP antibody testing not earlier than 30 days after the last case and in any case not earlier than 30 days after the last *vaccination*.

~~Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.~~

~~Serological testing is a suitable tool for FMD *surveillance*. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV *infection*/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical *surveillance*. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any presumptive positive serological test results. In areas where *animals* have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However,~~

~~NSP antibody tests should be used to monitor for FMDV *infection*/circulation. NSP-ELISAs may be used for screening sera for evidence of *infection*/circulation irrespective of the vaccination status of the *animal*.~~

Positive FMDV antibody test results can have five possible causes:

a) *infection* with FMDV;

b) *vaccination* against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some species, maternal antibodies can be detected for longer periods);

d) non-specific reactivity of the serum;

e) lack of specificity of the diagnostic tests used.

Procedure in case of positive test results

All seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimize false positive test reactors. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The number and strength of sero reactors should be taken into account.

All *herds* with ~~seropositive~~ at least one *laboratory* confirmed reactor~~s~~ should be investigated immediately. ~~Epidemiological and supplementary *laboratory* investigation results should document the status of FMDV *infection*/circulation for each positive *herd*.~~ The investigation should examine all evidence, including the results of virological tests that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to virus circulation and should document the status of FMDV *infection*/circulation for each positive *herd*. Epidemiological investigation should be continued in parallel.

Clustering of seropositive reactions should be investigated as it may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of *infection*/circulation. As clustering may signal *infection*/circulation, the investigation of all instances must be incorporated in the survey design.

Paired serology can be used to identify virus circulation by demonstrating an increase in the number of seropositive *animals* or an increase in antibody titre at the second sampling.

The investigation should include the reactor *animal(s)*, susceptible *animals* of the same *epidemiological unit* and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)*. The *animals* sampled should remain in the holding pending test results, should be clearly identifiable, accessible and should not be vaccinated during the investigations, so that they can be retested after an adequate period of time. Following clinical examination, a second sample should be taken from the *animals* tested in the initial survey with emphasis on *animals* in direct contact with the reactor(s) after an adequate interval of time has lapsed. If the *animals* are not individually identified, a new serological survey should be carried out in the holding(s) after an adequate period of time, repeating the application of the primary survey design. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and preferably belonging to the same species resident within the initial positive sampling units. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the *animals* of the *epidemiological* unit under investigation for at least two *incubation periods* and should remain serologically negative if virus is not circulating.

~~Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should approach that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.~~

~~Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.~~

~~3. The follow-up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination country or, zone where vaccination is not practised~~

~~Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and, where possible, virological investigations of the reactor *animal* at hand, of susceptible *animals* of the same *epidemiological unit* and of susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal*. If the follow-up investigations provide no evidence FMDV infection, the reactor *animal* shall be classified as FMD negative. In all other cases including the absence of such follow-up investigations, the reactor *animal* should be classified as FMD positive.~~

If circulation is proved then the *outbreak* is declared.

In the absence of FMDV circulation, an *outbreak* can be ruled out, but the significance of FMD positive *animals* is difficult to classify. Such findings can be an indication of acute *infection* followed by recovery or by the development of the carrier state, in ruminants, or due to non-specific reaction or lack of specificity of the diagnostic tests used. Antibodies to NSP may be induced by repeat *vaccination* with vaccines that do not comply with the requirements for purity. However the use of such vaccines is not permissible for countries, *zones* or *compartments* applying for an official status.

In the case of a vaccinated *herd* in a country, *zone* or *compartment* trying to establish or re-establish the status of an FMD free country, *zone* or *compartment* where *vaccination* is practised, the follow-up investigations may be considered completed where the *herd* can be declared free of FMDV circulation. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.

In all other cases, when a small number of FMD positive *animals* are found, at a level consistent with the expected number of non-specific test system findings, it is recommended that such reactor *animals* should be slaughtered, and then the *herd* declared free of FMDV *infection*. In the case of a number of FMD positive *animals* at a level above the expected number of non-specific test system findings, it is recommended that the *herd* should be slaughtered and susceptible *animals* that have been in contact or otherwise epidemiologically associated with the reactor *animal(s)* should be investigated.

~~4. The follow-up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free country or zone where vaccination is practised status with vaccination~~

~~In case of vaccinated populations, one has to exclude that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from *surveillance* conducted on FMD vaccinated populations.~~

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.

It is suggested that in the primary sampling units where at least one *animal* reacts positive to the NSP test, the following strategy(ies) should be applied:

a) Following clinical examination, a second serum sample should be taken from the *animals* tested in the initial survey after an adequate interval of time has lapsed, on the condition that they are individually identified, accessible and have not been vaccinated during this period. The number of *animals* with antibodies against NSP in the population at the time of retest should be statistically either equal to or less than that observed in the initial test if virus is not circulating.

   The *animals* sampled should remain in the holding pending test results and should be clearly identifiable. If the three conditions for retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all *animals* tested are individually identified. These *animals* should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

b) Following clinical examination, serum samples should be collected from representative numbers of susceptible *animals* that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating.

c) Following clinical examination, epidemiologically linked *herds* should be serologically tested and satisfactory results should be achieved if virus is not circulating.

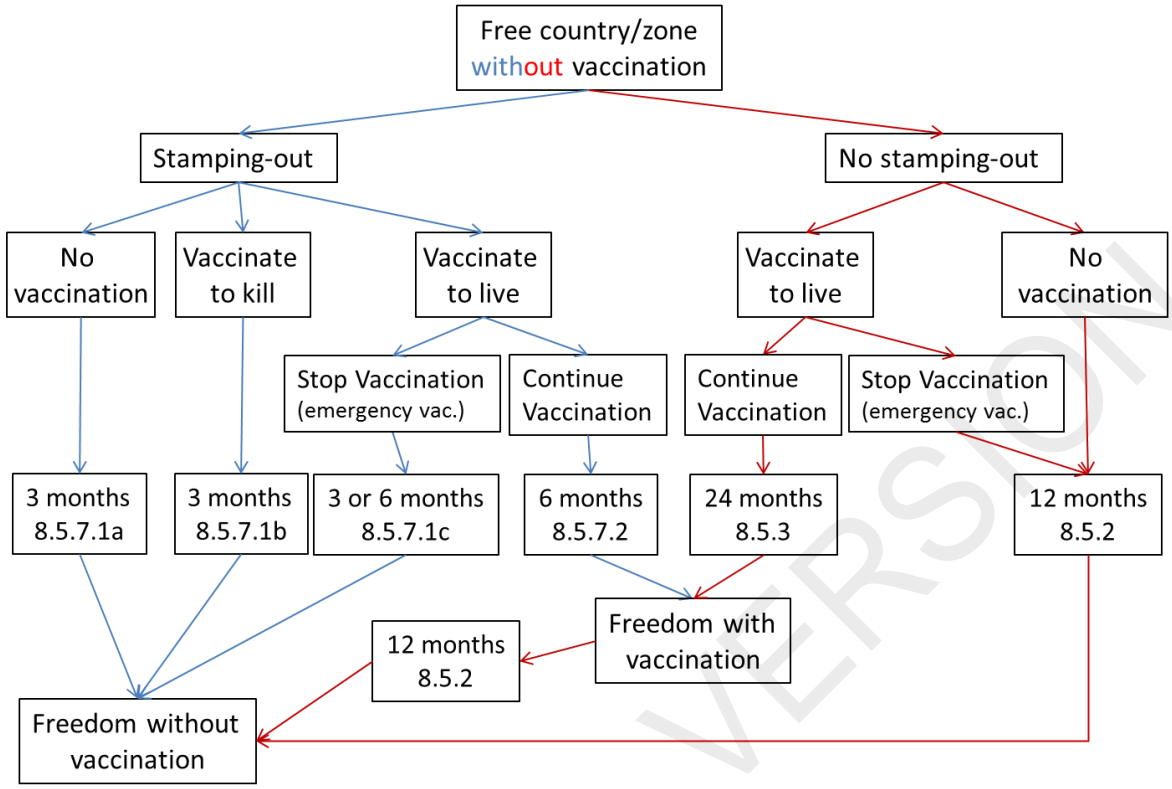
d) Sentinel *animals* can also be used. These can be young, unvaccinated *animals* or *animals* in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating. If other susceptible, unvaccinated *animals* are present, they could act as sentinels to provide additional serological evidence.

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

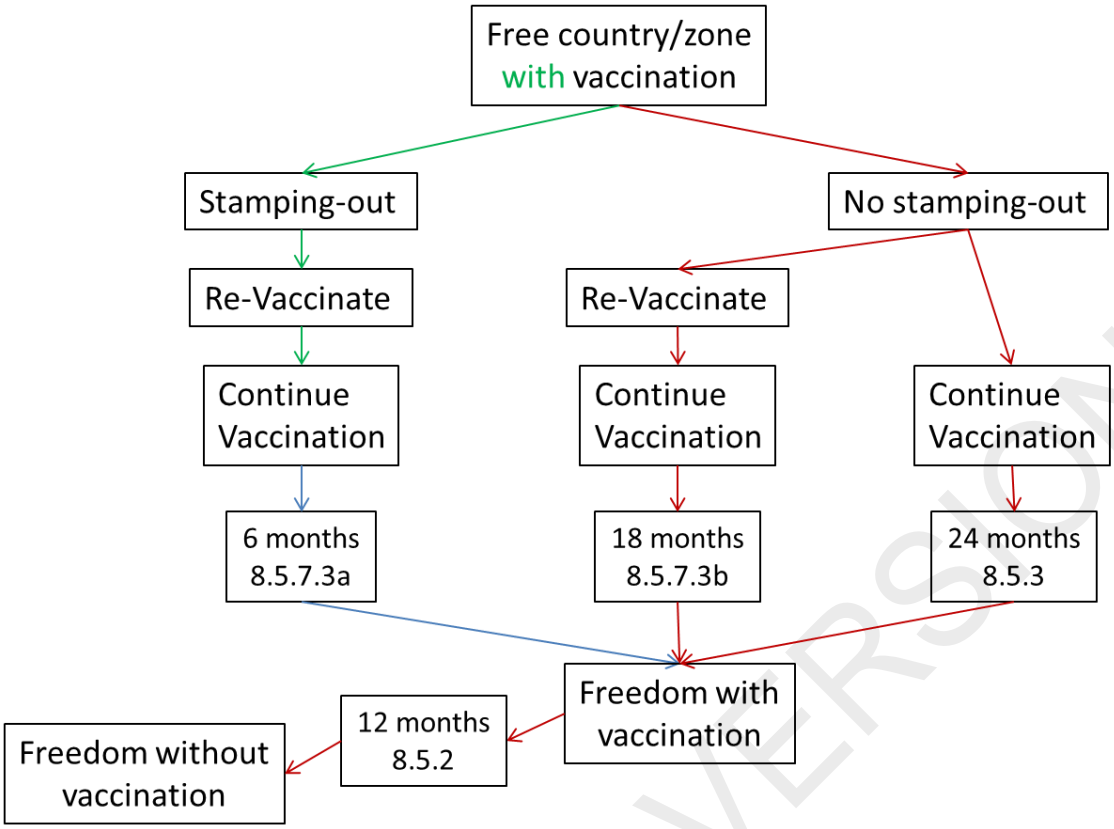
- characterization of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- quantification of *vaccinations* performed on the affected sites;
- sanitary protocol and history of the *establishments* with positive reactors;
- control of *animal identification* and movements;
- other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the *surveillance* programme.

Figure 1: Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status



**Waiting periods are minima depending upon outcome of surveillance specified in respective Articles*



**Waiting periods are minima depending upon outcome of surveillance specified in respective Articles*

Figure ~~1~~2: Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys